Disability Evaluation Under Social Security

foreword

This new edition of *Disability Evaluation Under Social Security* has been specially prepared to keep physicians and other health professionals up to date with the latest changes in the disability insurance program (title II of the Social Security Act), and the supplemental security income program (title XVI of the Social Security Act). The new edition includes:

- An expanded general discussion of the title II and title XVI disability programs, including answers to commonly asked questions about the disability programs (Part I);
- A new section on evidentiary requirements (Part II); and
- An updated version of the Listing of Impairments, which contains the revised respiratory, cardiovascular and immune system listings for both adults and children (Part III).

This new publication obsoletes and replaces the October 1992 edition of *Disability Evaluation Under Social Security.* It is intended to provide physicians and other health professionals with an understanding of the disability programs administered by the Social Security Administration, how each program works, and the kinds of medical information a health professional can furnish to help ensure sound and prompt decisions on disability claims.

In order to provide information that is as up-to-date as possible, the Social Security Administration intends to revise this publication, or parts of it, on an annual basis.

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table of contents

table of contents (continued)

Part I
General Information

General Information

Program Description

The Social Security Administration (SSA) administers two programs that provide benefits based on disability: the Social Security disability insurance program (title II of the Social Security Act (the Act)) and the supplemental security income (SSI) program (title XVI of the Act).

Title II provides for payment of disability benefits to individuals who are "insured" under the Act by virtue of their contributions to the Social Security trust fund through the Social Security tax on their earnings, as well as to certain disabled dependents of insured individuals. Title XVI provides for SSI payments to individuals (including children under age 18) who are disabled and have limited income and resources.

The Act and SSA's implementing regulations prescribe rules for deciding if an individual is "disabled." SSA's criteria for deciding if someone is disabled are not necessarily the same as the criteria applied in other Government and private disability programs.

Definition of Disability

For all individuals applying for disability benefits under title II, and for adults applying under title XVI, the definition of disability is the same. The law defines disability as the inability to engage in any substantial gainful activity by reason of any medically determinable physical or mental impairment(s) which can be expected to result in death or which has lasted or can be expected to last for a continuous period of not less than 12 months.

Disability in Children

Under title XVI, a child under age 18 may be considered disabled if he or she has a medically determinable impairment(s) that is of comparable severity. An impairment(s) is of comparable severity if it limits the child's ability to function independently, appropriately, and effectively in an age-appropriate manner such that his or her impairment(s) and the limitations resulting from it are comparable to those which would disable an adult.

What is a "Medically Determinable Impairment"

A medically determinable physical or mental impairment is an impairment that results from anatomical, physiological, or psychological abnormalities which can be shown by medically acceptable clinical and laboratory diagnostic techniques. A physical or mental impairment must be established by medical evidence consisting of signs, symptoms, and laboratory findings-- not only by the individual's statement of symptoms.

The Disability Determination Process

Most disability claims are initially processed through a network of local Social Security field offices and State agencies (usually called disability determination services, or DDSs). Subsequent appeals of unfavorable determinations may be decided by in the DDSs or by administrative law judges in SSA's Office of Hearings and Appeals.

Social Security Field Offices

SSA representatives in the field offices usually obtain applications for disability benefits, either in person, by telephone, or by mail. The application and related forms ask for a description of the claimant's impairment(s), names, addresses, and telephone numbers of treatment sources, and other information that relates to the alleged disability. (The "claimant" is the person who is requesting disability benefits)

The field office is responsible for verifying nonmedical eligibility requirements, which may include age, employment, marital status, or Social Security coverage information. The field office sends the case to a DDS for evaluation of disability.

State Disability Determination Services

The DDSs, which are fully funded by the Federal Government, are State agencies responsible for developing medical evidence and rendering the initial determination on whether the claimant is or is not disabled or blind under the law.

Usually, the DDS tries to obtain evidence from the claimant's own medical sources first. If that evidence is unavailable or insufficient to make a determination, the DDS will arrange for a consultative examination (CE) in order to obtain the additional information needed. The claimant's treating source is the preferred source for the CE; however, the DDS may also obtain the CE from an independent source. (See Part II, Evidentiary Requirements, for more information about CEs.)

After completing its initial development, the DDS makes the disability determination. The determination is made by a two-person adjudicative team consisting of a medical or psychological consultant (who is a physician or psychologist) and a disability examiner. If the adjudicative team finds that additional evidence is still needed, the consultant or examiner may recontact a medical source(s) and ask for supplemental information.

The DDS also makes a determination whether the claimant is a candidate for vocational rehabilitation (VR). If so, the DDS makes a referral to the State VR agency.

After the DDS makes the disability determination, it returns the case to the field office for appropriate action depending on whether the claim is allowed or denied. If the DDS finds the claimant disabled, SSA will complete any outstanding non-disability development, compute the benefit amount, and begin paying benefits. If the claimant is found not disabled, the file is retained in the field office in case the claimant decides to appeal the determination.

If the claimant files an appeal of an initial unfavorable determination, the appeal is usually handled much the same as the initial claim, except that the disability determination is made by a different adjudicative team in the DDS than the one that handled the original case.

Office of Hearings and Appeals

Claimants dissatisfied with the first appeal of a determination may file subsequent appeals. The second appeal is processed by a Hearing Office within SSA's Office of Hearings and Appeals. An administrative law judge makes the second appeal decision, usually after conducting a hearing and receiving any additional evidence from the claimant's medical sources or other sources.

Medical development by the Office of Hearings and Appeals is frequently conducted through the DDS. However, hearing offices may also contact medical sources directly. In rare circumstances, an administrative law judge may issue a subpoena requiring production of evidence or testimony at a hearing.

The Role of the Health Professional

Health professionals play a vital role in the disability determination process and participate in the process in a variety of ways:

- As treating sources or other medical sources who provide medical evidence on behalf of their patients;
- As CE sources to perform, for a fee, examinations and/or tests that are needed;
- As full- or part-time medical or psychological consultants reviewing claims in a DDS, in one of SSA's regional offices, or in SSA central office; or
- As medical experts who testify at administrative law judge hearings.

Treating Sources

A treating source is a claimant's own physician, psychologist, or other acceptable medical source who has provided the claimant with medical treatment or evaluation and has or has had an ongoing treatment relationship with the claimant. The treating source is usually the best source of medical evidence about the nature and severity of an individual's impairment(s).

If an additional examination or testing is needed, SSA usually considers a treating source to be the preferred source for performing the examination or test for his or her own patient.

The treating source is neither asked nor expected to make a decision whether the claimant is disabled. However, a treating source will usually be asked to provide a statement about the claimant's ability, despite his or her impairments, to do work-related physical or mental activities.

Consultative Examiners for the DDS

In the absence of sufficient medical evidence from a claimant's own medical sources, SSA, through the State DDS, may request an additional examination(s). These CEs are performed by physicians (including osteopaths), psychologists or, in certain circumstances, other health professionals. All CE sources must be currently licensed in the State and have the training and experience to perform the type of examination or test SSA requests.

Fees for CEs are set by each State and may vary from State to State. Each State agency is responsible for comprehensive oversight management of its CE program.

Medical professionals who perform CEs must have a good understanding of SSA's disability programs and their evidentiary requirements. In addition, these medical professionals are made fully aware of their responsibilities and obligations regarding confidentiality and:

- CE scheduling intervals;
- CE report content;
- Elements of a complete CE;
- When a complete CE is not required; and
- Signature requirements.

See Part II for more information about CEs.

Program Medical Professionals

Physicians of virtually all specialties and psychologists at the State, regional, or national levels review claims for disability benefits. The review work is performed in the State DDSs or SSA's regional office or headquarters. It is strictly a paper review in which the program physician or psychologist usually has no contact with the claimant.

Medical Experts

Because there is no direct involvement of medical professionals in the disability decisions made by administrative law judges in the Office of Hearings and Appeals, administrative law judges sometimes request expert testimony on complex medical issues. Each Hearing Office maintains a roster of medical experts who are called to testify as expert witnesses at hearings. The experts are paid a fee for their services.

Confidentiality of Records

Two separate laws, the Freedom of Information Act and the Privacy Act, have special significance for Federal agencies. Under the Freedom of Information Act, Federal agencies are required to provide the public with access to their files and records. This means the public has the right, with certain exceptions, to examine records pertaining to the functions, procedures, final opinions, and policy of these Federal agencies.

The Privacy Act permits an individual or his or her authorized representative to examine records pertaining to him or her in a Federal agency. For disability applicants, this means that an individual may request to see the medical or other evidence used to evaluate his or her application for disability benefits under the Social Security or the SSI programs. (This evidence, however, is not available to the general public.)

SSA screens all requests to see medical evidence in a claim file to determine if release of the evidence directly to the individual might have an adverse effect on that individual. If so, the report will be released only to an authorized representative designated by the individual.

Questions and Answers About Social Security Disability Programs

This information is designed to provide a more thorough understanding of the disability programs administered by SSA. Following are some of the most frequent questions asked about these programs.

Q. Who can get disability benefits under Social Security?

A. Under the Social Security disability insurance program (title II of the Act), there are three basic categories of individuals who can qualify for benefits on the basis of disability:

- A disabled insured worker under 65.
- A person disabled since childhood (before age 22) who is a dependent of a deceased insured parent or a parent entitled to title II disability or retirement benefits.
- A disabled widow or widower age 50-60 if the deceased spouse was insured under Social Security.

Under title XVI, or SSI, there are two basic categories under which a financially needy person can get payments on the basis of disability:

- An adult age 18 or over who is disabled.
- A child (under age 18) who is disabled.

Q. How is the disability determination made?

A. SSA's regulations provide for disability evaluation under a procedure known as the "sequential evaluation process." For adults, this process requires sequential review of the claimant's current work activity, the severity of his or her impairment(s), the claimant's residual functional capacity, his or her past work, and his or her age, education, and work experience. For children applying for SSI, the process requires sequential review of the child's current work activity (if any), the severity of his or her impairment(s), and an individualized functional assessment. If an adult or child is found disabled or not disabled at any point in the evaluation, the evaluation does not continue.

Q. When do disability benefits start?

A. The law provides that, under the Social Security disability program, disability benefits for workers and widows usually cannot begin for 5 months after the established onset of the disability. The 5 month waiting period does not apply to individuals filing as children of workers. Under SSI, disability payments may begin as early as the date the individual files an application.

In addition, under the SSI disability program, an applicant may be found "presumptively disabled," and receive cash payments for up to 6 months while the formal disability determination is made. The presumptive payment is designed to allow a needy individual to meet his or her basic living expenses during the time it takes to process the application. If it is finally determined that the individual is not disabled, he or she is not required to refund the payments. There is no provision for a finding of presumptive disability under the title II program.

Q. What can an individual do if he or she disagrees with the determination?

A. If an individual disagrees with the initial determination in the case, he or she may appeal it. The first administrative appeal is a *reconsideration*, which is generally a case review at the State level by an adjudicative team that was not involved in the original determination. If dissatisfied with the reconsideration determination, the individual may request a *hearing* before an administrative law judge. If he or she is dissatisfied with the hearing decision, the final administrative appeal is for review by the *Appeals Council*. In general, a claimant has 60 days to appeal an unfavorable determination or decision. Appeals must be filed in writing and may be submitted by mail or in person to any Social Security office.

If the individual exhausts all administrative appeals, but wishes to continue pursuing the case, he or she may file a civil suit in Federal District Court and eventually appeal all the way to the United States Supreme Court.

Q. Can individuals receiving disability benefits or payments get Medicare or Medicaid coverage?

A. Medicare helps pay hospital and doctor bills of disabled or retired people who have worked long enough under Social Security to be insured for Social Security benefits. It generally covers people who are 65 and over; people who have been determined to be disabled and have been receiving benefits for at least 24 months; and people who need long-term dialysis treatment for chronic kidney disease or require a kidney transplant. In general, Medicare pays 80 percent of reasonable charges.

In most States, individuals who qualify for SSI disability payments also qualify for Medicaid. (The name varies in some States--the term "Medicaid" is not used everywhere.) The program covers all of the approved charges of the Medicaid patient. Medicaid is financed by Federal and State matching funds, but eligibility rules may vary from State to State.

Q. Can someone work and still receive disability benefits?

A. Social Security rules make it possible for people to test their ability to work without losing their rights to cash benefits and Medicare or Medicaid. These rules are called "work incentives." The rules are different for title II and title XVI, but under both programs they may provide:

- continued cash benefits;
- continued help with medical bills;
- help with work expenses; or
- vocational training.

For more information about work incentives, ask any Social Security office for the publication: "A Summary Guide to Social Security and Supplemental Security Income Work Incentives for People with Disabilities."

Q. How can the individual receive vocational training services?

A. Applicants for disability payments may be referred to a State VR agency for rehabilitation services. The referral may be made by the DDS, Social Security, the treating source, or by personal request. The services may be medical or nonmedical and may include counseling, teaching of new employment skills, training in the use of prostheses, and job placement. In determining whether VR services would be beneficial in returning a person to employment, the medical evidence from the treating source may be very important.

PART II
EVIDENTIARY REQUIREMENTS

EVIDENTIARY REQUIREMENTS

Medical Evidence

Under both the title II and title XVI programs, *medical evidence* is the cornerstone for the determination of disability.

Each person who files a disability claim is responsible for providing medical evidence showing that he or she has an impairment(s) and how severe the impairment(s) is. However, SSA will help claimants get medical reports from their own medical sources when the claimants gives SSA permission to do so. This medical evidence generally comes from sources who have treated or evaluated the claimant for his or her impairment(s).

Acceptable Medical Sources

Documentation of the existence of a claimant's impairment must come from medical professionals defined by SSA's regulation as "acceptable medical sources." Once the existence of an impairment is established, all the medical and nonmedical evidence is considered in assessing impairment severity.

"Acceptable medical sources" generally include licensed physicians (including licensed osteopaths), licensed or certified psychologists, and licensed optometrists (for measurement of visual acuity and visual fields). Social Security also requests copies of medical evidence from hospitals, clinics, or other health facilities where a claimant has been treated. All medical reports received are considered during the disability determination process.

Medical Evidence From Treating Sources

Currently, many disability claims are decided on the basis of medical evidence from treating sources. SSA regulations place special emphasis on evidence from treating sources because they are likely to be the medical professionals most able to provide a detailed, longitudinal picture of the claimant's impairments and may bring a unique perspective to the medical evidence that cannot be obtained from the medical findings alone or from reports of individual examinations or brief hospitalizations. Therefore, timely, accurate, and adequate medical reports from treating sources accelerate the processing of the claim because they can greatly reduce or eliminate the need for additional medical evidence to complete the claim.

Other Evidence

Information from other sources may also help show the extent to which a person's impairment(s) affects his or her ability to function. Other sources include public and private social welfare agencies, non-medical sources such as teachers, day care providers, social workers and employers, and other practitioners such as naturopaths, chiropractors, audiologists, and speech and language pathologists.

Medical Reports

Physicians, psychologists, and other health professionals are frequently asked by SSA to submit reports about an individual's impairment. Therefore, it is important to know what evidence SSA needs. Medical reports should include:

- medical history;
- clinical findings (such as the results of physical or mental status examinations);
- laboratory findings (such as blood pressure, x-rays);
- diagnosis;
- treatment prescribed with response and prognosis;
- a statement providing an opinion about what the claimant can still do despite his or her impairment(s), based on the medical source's findings on the above factors. This statement should describe, but is not limited to, the individual's ability to perform work-related activities, such as sitting, standing, walking, lifting, carrying, handling objects, hearing, speaking, and traveling. In cases involving mental impairments, it should describe the individual's ability to understand, to carry out and remember instructions, and to respond appropriately to supervision, coworkers, and work pressures in a work setting. For a child, the statement should describe the child's ability to function independently, appropriately, and effectively in an age-appropriate manner in the domains and behaviors appropriate for the child's age.

Consultative Examinations

If the evidence provided by the claimant's own medical sources is inadequate to determine if he or she is disabled, additional medical information may be sought by recontacting the treating source for additional information or clarification, or by arranging for a CE. The treating source is the preferred source for a CE if he or she is qualified, equipped, and willing to perform the examination for the authorized fee. Even if only a supplemental test is required, the treating source is ordinarily the preferred source for this service. However, SSA's rules provide for using an independent source (other than the treating source) for a CE or diagnostic study if:

- the treating source prefers not to perform these examination;
- the treating source does not have the equipment to provide the specific data needed;
- there are conflicts or inconsistencies in the file that cannot be resolved by going back to the treating source;
- the claimant prefers another source and has a good reason for doing so; or
- prior experience indicates that the treating source may not be a productive source.

Consultative Examination Report Content

A complete CE is one which involves all the elements of a standard examination in the applicable medical specialty. When the report of a complete consultative examination is involved, the report should include the following elements:

- the claimant's major or chief complaint(s);
- a detailed description, within the area of specialty of the examination, of the history of the major complaint(s);
- a description, and disposition, of pertinent "positive" and "negative" detailed findings based on the history, examination, and laboratory tests related to the major complaint(s), and any other abnormalities or lack thereof reported or found during examination or laboratory testing;
- the results of laboratory and other tests (e.g., X-rays) performed according to the requirements stated in the Listing of Impairments (see Part III);
- the diagnosis and prognosis for the claimant's impairment(s);
- a statement about what the claimant can still do despite his or her impairment(s), unless the claim is based on statutory blindness. This statement should describe the opinion of the consulting physician or psychologist about the claimant's ability, despite his or her impairment(s), to do work-related activities such as sitting, standing, walking, lifting, carrying, handling objects, hearing, speaking, and traveling; and, in cases of mental impairment(s), the opinion of the physician or psychologist about the individual's ability to understand, to carry out and remember instructions, and to respond appropriately to supervision, coworkers, and work pressures in a work setting; and
- the consultative physician or psychologist will consider, and provide some explanation or comment on, the claimant's major complaint(s) and any other abnormalities found during the history and examination or reported from the laboratory tests. The history, examination, evaluation of laboratory test results, and the conclusions will represent the information provided by the physician or psychologist who signs the report.

Evidence Relating to Symptoms

In developing evidence of the effects of symptoms, such as pain, shortness of breath, or fatigue, on a claimant's ability to function, SSA investigates all avenues presented that relate to the complaints. These include information provided by treating and other sources regarding:

- the claimant's daily activities;
- the location, duration, frequency, and intensity of the pain or other symptom;
- precipitating and aggravating factors;
- the type, dosage, effectiveness, and side effects of any medication;
- treatments, other than medications, for the relief of pain or other symptoms;
- any measures the claimant uses or has used to relieve pain or other symptoms; and
- other factors concerning the claimant's functional limitations due to pain or other symptoms.

In assessing the claimant's pain or other symptoms, the decisionmaker(s) must give full consideration to all of the above-mentioned factors. It is important that medical sources address these factors in the reports they provide.

PART III
LISTING OF IMPAIRMENTS

Listing of Impairments

The Listing of Impairments describes, for each major body system, impairments which are considered severe enough to prevent a person from doing any gainful activity, (or in the case of children under age 18 applying for SSI, are comparable in severity to an impairment that would preclude an adult from engaging in any gainful activity). Most of the listed impairments are permanent or expected to result in death, or a specific statement of duration is made. For all others, the evidence must show that the impairment has lasted or is expected to last for a continuous period of at least 12 months. The criteria in the Listing of Impairments are applicable to evaluation of claims for disability benefits or payments under both the Social Security disability insurance and SSI programs.

Part A of the Listing of Impairments contains medical criteria that apply to adults age 18 and over. The medical criteria in part A may also be applied in evaluating impairments in persons under age 18 if the disease processes have a similar effect on adults and younger persons.

Part B contains additional medical criteria that apply only to the evaluation of impairments of persons under age 18. Certain criteria in part A do not give appropriate consideration to the particular effects of the disease processes in childhood, i.e., when the disease process is generally found only in children or when the disease process differs in its effect on children and adults. Additional criteria are included in part B, and the impairment categories are, to the extent possible, numbered to maintain a relationship with their counterparts in part A. In evaluating disability for a person under age 18, part B will be used first. If the medical criteria in part B do not apply, then the medical criteria in part A will be used.

The criteria in the Listing of Impairments apply only to one step of the multi-step sequential evaluation process. At that step, the presence of an impairment that meets the criteria in the Listing of Impairments (or that is of equal severity) is usually sufficient to establish that an individual who is not working is disabled. However, the absence of a listing-level impairment does not mean the individual is not disabled. Rather, it merely requires the adjudicator to move on to the next step of the process and apply other rules in order to resolve the issue of disability.

Listing of Impairments

PART A

The following sections in Part A are applicable to individuals age 18 and over and to children under age 18 where criteria are appropriate.

Sec.

1.00 MUSCULOSKELETAL SYSTEM

A. *Loss of function* may be due to amputation or deformity. Pain may be an important factor in causing functional loss, but it must be associated with relevant abnormal signs or laboratory findings. Evaluations of musculoskeletal impairments should be supported where applicable by detailed descriptions of the joints, including ranges of motion, condition of the musculature, sensory or reflex changes, circulatory deficits, and X-ray abnormalities.

B. *Disorders of the spine,* associated with vertebrogenic disorders as in 1.05C, result in impairment because of distortion of the bony and ligamentous architecture of the spine or impingement of a herniated nucleus pulposus or bulging annulus on a nerve root. Impairment caused by such abnormalities usually improves with time or responds to treatment. Appropriate abnormal physical findings must be shown to persist on repeated examinations despite therapy for a reasonable presumption to be made that severe impairment will last for a continuous period of 12 months. This may occur in cases with unsuccessful prior surgical treatment.

Evaluation of the impairment caused by disorders of the spine requires that a clinical diagnosis of the entity to be evaluated first must be established on the basis of adequate history, physical examination, and roentgenograms. The specific findings stated in 1.05C represent the level required for that impairment; these findings, by themselves are not intended to represent the basis for establishing the clinical diagnosis. Furthermore, while neurological examination findings are required, they are not to be interpreted as a basis for evaluating the magnitude of any neurological impairment. Neurological impairments are to be evaluated under 11.00-11.19.

The history must include a detailed description of the character, location, and radiation of pain; mechanical factors which incite and relieve pain; prescribed treatment, including type, dose, and frequency of analgesic; and typical daily

activities. Care must be taken to ascertain that the reported examination findings are consistent with the individual's daily activities.

There must be a detailed description of the orthopedic and neurologic examination findings. The findings should include a description of gait, limitation of movement of the spine given quantitatively in degrees from the vertical position, motor and sensory abnormalities, muscle spasm, and deep tendon reflexes. Observations of the individual during the examination should be reported; e.g., how he or she gets on and off the examining table. Inability to walk on heels or toes, to squat, or to arise from a squatting position, where appropriate, may be considered evidence of significant motor loss. However, a report of atrophy is not acceptable as evidence of significant motor loss without circumferential measurements of both thighs and lower legs(or upper or lower arms) at a stated point above and below the knee or elbow given in inches or centimeters. A specific description of atrophy of hand muscles is acceptable without measurements of atrophy but should include measurements of grip strength.

These physical examination findings must be determined on the basis of objective observations during the examination and not simply a report of the individual's allegation, e.g., he says his leg is weak, numb, etc. Alternative testing methods should be used to verify the objectivity of the abnormal findings, e.g., a seated straight-leg raising test in addition to a supine straight-leg raising test. Since abnormal findings may be intermittent, their continuous presence over a period of time must be established by a record of ongoing treatment. Neurological abnormalities may not completely subside after surgical or nonsurgical treatment, or with the passage of time. Residual neurological abnormalities, which persist after it has been determined clinically or by direct surgical or other observation that the ongoing or progressive condition is no longer present, cannot be considered to satisfy the required findings in 1.05C.

Where surgical procedures have been performed, documentation should include a copy of the operative note and available pathology reports.

Electrodiagnostic procedures and myelography may be useful in establishing the clinical diagnosis, but do not constitute alternative criteria to the requirements in section 1.05C.

C. *After maximum benefit from surgical therapy* has been achieved in situations involving fractures of an upper extremity (see 1.12), or soft tissue injuries of a lower or upper extremity (see 1.13), i.e., there have been no significant changes in physical findings or X-ray findings for any 6-month period after the last definitive surgical procedure, evaluation should be made on the basis of demonstrable residuals.

D. *Major joints* as used herein refer to hip, knee, ankle, shoulder, elbow, or wrist and hand. (Wrist and hand are considered together as one major joint.)

E. *The measurements of joint motion* are based on the techniques described in the "Joint Motion Method of Measuring and Recording," published by the American Academy of Orthopedic Surgeons in 1965, or the "Guides to the Evaluation of Permanent Impairment-The Extremities and Back" (Chapter I); American Medical Association, 1971.

1.01 CATEGORY OF IMPAIRMENTS, MUSCULOSKELETAL

1.02 *Active rheumatoid arthritis and other inflammatory arthritis.*

With both A and B:

A. History of persistent joint pain, swelling, and tenderness involving multiple major joints (see 1.00D) and with signs of joint inflammation (swelling and tenderness) on current physical examination despite prescribed therapy for at least 3 months, resulting in significant restriction of function of the affected joints, and clinical activity expected to last at least 12 months; and

B. Corroboration of diagnosis at some point in time by either:

1. Positive serologic test for rheumatoid factor; or
2. Antinuclear antibodies; or
3. Elevated sedimentation rate; or
4. Characteristic histologic changes in biopsy of synovial membrane or subcutaneous nodule (obtained independent of Social Security disability evaluation).

1.03 *Arthritis of a major weight-bearing joint (due to any cause):*

With history of persistent joint pain and stiffness with signs of marked limitation of motion or abnormal motion of the affected joint on current physical examination. With:

A. Gross anatomical deformity of hip or knee (e.g., subluxation, contracture, bony or fibrous ankylosis, instability) supported by x-ray evidence of either significant joint space narrowing or significant bony destruction and markedly limiting ability to walk and stand; or

B. Reconstructive surgery or surgical arthrodesis of a major weight-bearing joint and return to full weight-bearing status did not occur, or is not expected to occur, within 12 months of onset.

1.04 *Arthritis of one major joint in each of the upper extremities (due to any cause):*

With history of persistent joint pain and stiffness, signs of marked limitation of motion of the affected joints on current physical examination, and X-ray evidence of either significant joint space narrowing or significant bony destruction. With:

A. Abduction and forward flexion (elevation) of both arms at the shoulders, including scapular motion, restricted to less than 90 degrees; or

B. Gross anatomical deformity (e.g., subluxation, contracture, bony or fibrous ankylosis, instability, ulnar deviation) and enlargement or effusion of the affected joints.

1.05 *Disorders of the spine:*

A. Arthritis manifested by ankylosis or fixation of the cervical or dorsolumbar spine at 30 degrees or more of flexion measured from the neutral position, with X-ray evidence of:

1. Calcification of the anterior and lateral ligaments; or

2. Bilateral ankylosis of the sacroiliac joints with abnormal apophyseal articulations; or

B. Osteoporosis, generalized (established by X-ray) manifested by pain and limitation of back motion and paravertebral muscle spasm with X-ray evidence of either:

1. Compression fracture of a vertebral body with loss of at least 50 percent of the estimated height of the vertebral body prior to the compression fracture, with no intervening direct traumatic episode; or

2. Multiple fractures of vertebrae with no intervening direct traumatic episode; or

C. Other vertebrogenic disorders (e.g., herniated nucleus pulposus, spinal stenosis) with the following persisting for at least 3 months despite prescribed therapy and expected to last 12 months. With both 1 and 2:

1. Pain, muscle spasm, and significant limitation of motion in the spine; and

2. Appropriate radicular distribution of significant motor loss with muscle weakness and sensory and reflex loss.

1.08 *Osteomyelitis or septic arthritis (established by X-ray);*

A. Located in the pelvis, vertebra, femur, tibia, or a major joint of an upper or lower extremity, with persistent activity or occurrence of at least two episodes of acute activity within a 5-month period prior to adjudication, manifested by local inflammatory, and systemic signs and laboratory findings (e.g., heat, redness, swelling, leucocytosis, or increased sedimentation rate) and expected to last at least 12 months despite prescribed therapy; or

B. Multiple localizations and systemic manifestations as in A above.

1.09 *Amputation or anatomical deformity* of (i.e., loss of major function due to degenerative changes associated with vascular or neurological deficits, traumatic loss of muscle mass or tendons and X-ray evidence of bony ankylosis at an unfavorable angle, joint subluxation or instability):

A. Both hands; or

B. Both feet; or

C. One hand and one foot.

1.10 *Amputation of one lower extremity* (at or above the tarsal region):

A. Hemipelvectomy or hip disarticulation; or

B. Amputation at or above the tarsal region due to peripheral vascular disease or diabetes mellitus; or

C. Inability to use a prosthesis effectively, without obligatory assistive devices, due to one of the following;

1. Vascular disease; or

2. Neurological complications (e.g., loss of position sense); or

3. Stump too short or stump complications persistent, or are expected to persist, for at least 12 months from onset; or

4. Disorder of contralateral lower extremity which markedly limits ability to walk and stand.

1.11 *Fracture of the femur, tibia, tarsal bone, or pelvis* with solid union not evident on X-ray and not clinically solid, when such determination is feasible, and return to full weight-bearing status did not occur or is not expected to occur within 12 months of onset.

1.12 Fractures of an upper extremity with non-union of a fracture of the shaft of the humerus, radius, or ulna under continuing surgical management directed toward restoration of functional use of the extremity and such function was not restored or expected to be restored within 12 months after onset.

1.13 Soft tissue injuries of an upper or lower extremity requiring a series of staged surgical procedures within 12 months after onset for salvage and/or restoration of major function of the extremity, and such major function was not restored or expected to be restored within 12 months after onset.

2.00 SPECIAL SENSES AND SPEECH

A. Ophthalmology

1. *Causes of Impairment.* Diseases or injury of the eyes may produce loss of central or peripheral vision. Loss of central vision results in inability to distinguish detail and prevents reading and fine work. Loss of peripheral vision restricts the ability of an individual to move about freely. The extent of impairment of sight should be determined by visual testing.

2. *Central Visual Acuity*. A loss of central visual acuity may be caused by impaired distant and/or near vision. However, for an individual to meet the level of severity described in 2.02 and 2.04, only the remaining central visual acuity for distance of the better eye with best correction based on the Snellen test chart measurement may be used. Correction obtained by special visual aids (e.g., contact lenses) will be considered if the individual has the ability to wear such aids.

3. *Field of vision.* Impairment of peripheral vision may result if there is contraction of the visual fields. The contraction may be either symmetrical or irregular. The extent of the remaining peripheral visual field will be determined

by usual perimetric methods at a distance of 330 mm. under illumination of not less than 7-foot candles. For the phakic eye (the eye with a lens), a 3 mm. white disc target will be used, and for the aphakic eye (the eye without a lens), a 6 mm. white disc target will be used. In neither instance should corrective spectacle lenses be worn during the examination but if they have been used, this fact must be stated.

Measurements obtained on comparable perimetric devices may be used; this does not include the use of tangent screen measurements. For measurements obtained using the Goldmann perimeter, the object size designation III and the illumination designation 4 should be used for the phakic eye, and the object size designation IV and illumination designation 4 for the aphakic eye.

Field measurements must be accompanied by notated field charts, a description of the type and size of the target and the test distance. Tangent screen visual fields are not acceptable as a measurement of peripheral field loss.

Where the loss is predominantly in the lower visual fields, a system such as the weighted grid scale for perimetric fields as described by B. Esterman (see Grid for Scoring Visual Fields, II. Perimeter, *Archives of Ophthalmology,* 79:400, 1968) may be used for determining whether the visual field loss is comparable to that described in Table 2.

4. *Muscle Function.* Paralysis of the third cranial nerve producing ptosis, paralysis of accommodation, and dilation and immobility of the pupil may cause significant visual impairment. When all the muscles of the eye are paralyzed including the iris and ciliary body (total ophthalmoplegia), the condition is considered a severe impairment provided it is bilateral. A finding of severe impairment based primarily on impaired muscle function must be supported by a report of an actual measurement of ocular motility.

5. *Visual Efficiency.* Loss of visual efficiency may be caused by disease or injury resulting in a reduction of central visual acuity or visual field. The visual efficiency of one eye is the product of the percentage of central visual efficiency and the percentage of visual field efficiency. (See Tables No. 1 and 2, following 2.09.)

6. *Special Situations.* Aphakia represents a visual handicap in addition to the loss of central visual acuity. The term monocular aphakia would apply to an individual who has had the lens removed from one eye, and who still retains the lens in the other eye, or to an individual who has only one eye which is aphakic. The term binocular aphakia would apply to an individual who has had both lenses removed. In cases of binocular aphakia, the central efficiency of the better eye will be accepted as 75 percent of its value. In cases of monocular aphakia, where the better eye is aphakic, the central visual efficiency will be accepted as 50 percent of the value. (If an individual has binocular aphakia, and the central visual acuity in the poorer eye can be corrected only to 20/200, or less, the central visual efficiency of the better eye will be accepted as 50 percent of its value.)

Ocular symptoms of systemic disease may or may not produce a disabling visual impairment. These manifestations should be evaluated as part of the underlying disease entity by reference to the particular body system involved.

7. *Statutory Blindness.* The term "statutory blindness" refers to the degree of visual impairment which defines the term "blindness" in the Social Security Act. Both 2.02 and 2.03A and B denote statutory blindness.

B. Otolaryngology

1. *Hearing Impairment.* Hearing ability should be evaluated in terms of the person's ability to hear and distinguish speech.

Loss of hearing can be quantitatively determined by an audiometer which meets the standards of the American National Standards Institute (ANSI) for air and bone conducted stimuli (i.e., ANSI S 3.6-1969 and ANSI S 3.13-1972, or subsequent comparable revisions) and performing all hearing measurements in an environment which meets the ANSI standard for maximal permissible background sound (ANSI S 3.1-1977).

Speech discrimination should be determined using a standardized measure of speech discrimination ability in quiet at a test presentation level sufficient to ascertain maximum discrimination ability. The speech discrimination measure (test) used, and the level at which testing was done must be reported.

Hearing tests should be preceded by an otolaryngologic examination and should be performed by or under the supervision of an otolaryngologist or audiologist qualified to perform such tests.

In order to establish an independent medical judgment as to the level of impairment in a claimant alleging deafness, the following examinations should be reported: Otolaryngologic examination, pure tone air and bone audiometry, speech reception threshold (SRT), and speech discrimination testing. A copy of reports of medical examination and audiologic evaluations must be submitted.

Cases of alleged "deaf mutism" should be documented by a hearing evaluation. Records obtained from a speech and hearing rehabilitation center or a special school for the deaf may be acceptable, but if these reports are not available, or are found to be inadequate, a current hearing evaluation should be submitted as outlined in the preceding paragraph.

2. *Vertigo associated with disturbances of labyrinthine - vestibular function, including Meniere's disease.* These disturbances of balance are characterized by an hallucination of motion or a loss of position sense and a sensation of dizziness which may be constant or may occur in paroxysmal attacks. Nausea, vomiting, ataxia, and incapacitation are frequently observed, particularly during the acute attack. It is important to differentiate the report of rotary vertigo from that of "dizziness" which is described as light-headedness, unsteadiness, confusion, or syncope.

Meniere's disease is characterized by paroxysmal attacks of vertigo, tinnitus, and fluctuating hearing loss. Remissions are unpredictable and irregular, but may be longlasting; hence, the severity of impairment is best determined after prolonged observation and serial reexaminations.

The diagnosis of a vestibular disorder requires a comprehensive neuro-otolaryngologic examination with a detailed description of the vertiginous episodes, including notation of frequency, severity, and duration of the attacks.

Pure tone and speech audiometry with the appropriate special examinations, such as Bekesy audiometry, are necessary. Vestibular function is accessed by positional and caloric testing, preferably by electronystagmography. When polytomograms, contrast radiography, or other special tests have been performed, copies of the reports of these tests should be obtained, in addition to reports of skull and temporal bone X-rays.

3. *Organic Loss of Speech.* Glossectomy or laryngectomy or cicatricial laryngeal stenosis due to injury or infection results in loss of voice production by normal means. In evaluating organic loss of speech (see 2.09), ability to produce speech by any means includes the use of mechanical or electronic devices. Impairment of speech due to neurologic disorders should be evaluated under 11.00-11.19.

2.01 CATEGORY OF IMPAIRMENTS, SPECIAL SENSES AND SPEECH

2.02 *Impairment of Central Visual Acuity.* Remaining vision in the better eye after best correction is 20/200 or less.

2.03 *Contraction of Peripheral Visual Fields in the Better Eye.*

A. To 10° or less from the point of fixation; or

B. So the widest diameter subtends an angle no greater than 20 degrees; or

C. To 20 percent or less visual field efficiency.

2.04 *Loss of Visual Efficiency.* Visual efficiency of better eye after best correction 20 percent or less. (The percent of remaining visual efficiency = the product of the percent of remaining central visual efficiency and the percent of remaining visual field efficiency.)

2.05 *Complete Homonymous Hemianopsia* (with or without macular sparing). Evaluate under 2.04.

2.06 *Total Bilateral Ophthalmoplegia.*

2.07 *Disturbance of Labyrinthine-Vestibular Function* (Including Meniere's disease), characterized by a history of frequent attacks of balance disturbance, tinnitus, and progressive loss of hearing. With both A and B:

A. Disturbed function of vestibular labyrinth demonstrated by caloric or other vestibular tests; and

B. Hearing loss established by audiometry.

2.08 *Hearing Impairments* (hearing not restorable by a hearing aid) manifested by:

A. Average hearing threshold sensitivity for air conduction of 90 decibels or greater, and for bone conduction to corresponding maximal levels, in the better

ear, determined by the simple average of hearing threshold levels at 500, 1000, and 2000 hz. (see 2.00B1); or

B. Speech discrimination scores of 40 percent or less in the better ear.

2.09 *Organic loss of Speech* due to any cause with inability to produce by any means speech which can be heard, understood, and sustained.

TABLE NO. 1.–Percentage of central visual efficiency corresponding to central visual acuity notations for distance in the phakic and aphakic eye (better eye).

Snellen		Percent Central Visual Efficiency		
English	Metric	Phakic[1]	Aphakic Monocular[2]	Aphakic Binocular[3]
20/16	6/5	100	50	75
20/20	6/6	100	50T75	
20/25	6/7.5	95	47	71
20/32	6/10	90	45	67
20/40	6/12	85	42	64
20/50	6/15	75	37	56
20/64	6/20	65	32	49
20/80	6/24	60	30	45
20/100	6/30	50	25	37
20/125	6/38	40	20	30
20/160	6/48	30	—	22
20/200	6/60	20	—	—

Column and Use

[1]Phakic–1. A lens is present in both eyes. 2. A lens is present in the better eye and absent in the poorer eye. 3. A lens is present in one eye and the other eye is enucleated.

[2]Monocular–1. A lens is absent in the better eye and present in the poorer eye. 2. The lenses are absent in both eyes; however, the central visual acuity in the poorer eye after best correction is 20/200 or less. 3. A lens is absent from one eye and the other eye is enucleated.

[3]Binocular –1. The lenses are absent from both eyes and the central visual acuity in the poorer eye after best correction is greater than 20/200.

TABLE NO. 2–Chart of visual field showing extent of normal field and method of computing percent of visual field efficiency.

Left Eye (0.S.) Right Eye (O.D.)

1. Diagram of right eye illustrates extent of normal visual field as tested on standard perimeter at 3/330 (3 mm. white disc at a distance of 330 mm.) under 7 foot-candles illumination. The sum of the eight principal meridians of this field total 500 degrees.

2. The percent of visual field efficiency is obtained by adding the number of degrees of the eight principal meridians of the contracted field and dividing by 500. Diagram of left eye illustrates visual field contracted to 30 degrees in the temporal and down and out meridians and to 20 degrees in the remaining six meridians. The percent of visual field efficiency of this field is: 6x20 + 2x30 = 180 divided by 500 = 0.36 or 36 percent remaining visual field efficiency, or 64 percent loss.

3.00 RESPIRATORY SYSTEM

A. *Introduction.* The listings in this section describe impairments resulting from respiratory disorders based on symptoms, physical signs, laboratory test abnormalities, and response to a regimen of treatment prescribed by a treating source. Respiratory disorders along with any associated impairment(s) must be established by medical evidence. Evidence must be provided in sufficient detail to permit an independent reviewer to evaluate the severity of the impairment.

Many individuals, especially those who have listing-level impairments, will have received the benefit of medically prescribed treatment. Whenever there is evidence of such treatment, the longitudinal clinical record must include a description of the treatment prescribed by the treating source and response in addition to information about the nature and severity of the impairment. It is important to document any prescribed treatment and response, because this medical management may have improved the individual's functional status. The longitudinal record should provide information regarding functional recovery, if any. Some individuals will not have received ongoing treatment or have an ongoing relationship with the medical community, despite the existence of a severe impairment(s). An individual who does not receive treatment may or may not be able to show the existence of an impairment that meets the criteria of these listings. Even if an individual does not show that his or her impairment meets the criteria of these listings, the individual may have an impairment(s) equivalent in severity to one of the listed impairments or be disabled because of a limited residual functional capacity. Unless the claim can be decided favorably on the basis of the current evidence, a longitudinal record is still important because it will provide information about such things as the ongoing medical severity of the impairment, the level of the individual's functioning, and the frequency, severity, and duration of symptoms. Also, the asthma listing specifically includes a requirement for continuing signs and symptoms despite a regimen of prescribed treatment.

Impairments caused by chronic disorders of the respiratory system generally produce irreversible loss of pulmonary function due to ventilatory impairments, gas exchange abnormalities, or a combination of both. The most common symptoms attributable to these disorders are dyspnea on exertion, cough, wheezing, sputum production, hemoptysis, and chest pain. Because these symptoms are common to many other diseases, a thorough medical history, physical examination, and chest x-ray or other appropriate imaging technique are required to establish chronic pulmonary disease. Pulmonary function testing is required to assess the severity of the respiratory impairment once a disease process is established by appropriate clinical and laboratory findings.

Alterations of pulmonary function can be due to obstructive airway disease (e.g., emphysema, chronic bronchitis, asthma), restrictive pulmonary disorders with primary loss of lung volume (e.g., pulmonary resection, thoracoplasty, chest cage deformity as in kyphoscoliosis or obesity), or infiltrative interstitial disorders (e.g., diffuse pulmonary fibrosis). Gas exchange abnormalities without significant airway obstruction can be produced by interstitial disorders. Disorders involving the pulmonary circulation (e.g., primary pulmonary hypertension, recurrent thromboembolic disease, primary or secondary pulmonary vasculitis) can produce pulmonary vascular hypertension and,

eventually, pulmonary heart disease (cor pulmonale) and right heart failure. Persistent hypoxemia produced by any chronic pulmonary disorder also can result in chronic pulmonary hypertension and right heart failure. Chronic infection, caused most frequently by mycobacterial or mycotic organisms, can produce extensive and progressive lung destruction resulting in marked loss of pulmonary function. Some disorders, such as bronchiectasis, cystic fibrosis, and asthma, can be associated with intermittent exacerbations of such frequency and intensity that they produce a disabling impairment, even when pulmonary function during periods of relative clinical stability is relatively well-maintained.

Respiratory impairments usually can be evaluated under these listings on the basis of a complete medical history, physical examination, a chest x-ray or other appropriate imaging techniques, and spirometric pulmonary function tests. In some situations, most typically with a diagnosis of diffuse interstitial fibrosis or clinical findings suggesting cor pulmonale, such as cyanosis or secondary polycythemia, an impairment may be underestimated on the basis of spirometry alone. More sophisticated pulmonary function testing may then be necessary to determine if gas exchange abnormalities contribute to the severity of a respiratory impairment. Additional testing might include measurement of diffusing capacity of the lungs for carbon monoxide or resting arterial blood gases. Measurement of arterial blood gases during exercise is required infrequently. In disorders of the pulmonary circulation, right heart catheterization with angiography and/or direct measurement of pulmonary artery pressure may have been done to establish a diagnosis and evaluate severity. When performed, the results of the procedure should be obtained. Cardiac catheterization will not be purchased.

These listings are examples of common respiratory disorders that are severe enough to prevent a person from engaging in a gainful activity. When an individual has a medically determinable impairment that is not listed, an impairment which does not meet a listing, or a combination of impairments no one of which meets a listing, we will consider whether the individual's impairment or combination of impairments is medically equivalent in severity to a listed impairment. Individuals who have an impairment(s) with a level of severity which does not meet or equal the criteria of the listings may or may not have the residual functional capacity (RFC) which would enable them to engage in substantial gainful activity. Evaluation of the impairment(s) of these individuals will proceed through the final steps of the sequential evaluation process.

B. *Mycobacterial, mycotic, and other chronic persistent infections of the lung.* These disorders are evaluated on the basis of the resulting limitations in pulmonary function. Evidence of chronic infections,such as active mycobacterial diseases or mycoses with positive cultures, drug resistance, enlarging parenchymal lesions, or cavitation, is not, by itself, a basis for determining that an individual has a disabling impairment expected to last 12 months. In those unusual cases of pulmonary infection that persist for a period approaching 12 consecutive months, the clinical findings, complications, therapeutic considerations, and prognosis must be carefully assessed to determine whether, despite relatively well-maintained pulmonary function, the individual nevertheless has an impairment that is expected to last for at least 12 consecutive months and prevent gainful activity.

C. Episodic respiratory disease. When a respiratory impairment is episodic in nature, as can occur with exacerbations of asthma, cystic fibrosis, bronchiectasis, or chronic asthmatic bronchitis, the frequency and intensity of episodes that occur despite prescribed treatment are often the major criteria for determining the level of impairment. Documentation for these exacerbations should include available hospital, emergency facility and/or physician records indicating the dates of treatment; clinical and laboratory findings on presentation, such as the results of spirometry and arterial blood gas studies (ABGS); the treatment administered; the time period required for treatment; and the clinical response. Attacks of asthma, episodes of bronchitis or pneumonia or hemoptysis (more than blood-streaked sputum), or respiratory failure as referred to in paragraph B of 3.03, 3.04, and 3.07, are defined as prolonged symptomatic episodes lasting one or more days and requiring intensive treatment, such as intravenous bronchodilator or antibiotic administration or prolonged inhalational bronchodilator therapy in a hospital, emergency room or equivalent setting. Hospital admissions are defined as inpatient hospitalizations for longer than 24 hours. The medical evidence must also include information documenting adherence to a prescribed regimen of treatment as well as a description of physical signs. For asthma, the medical evidence should include spirometric results obtained between attacks that document the presence of baseline airflow obstruction.

D. *Cystic fibrosis* is a disorder that affects either the respiratory or digestive body systems or both and is responsible for a wide and variable spectrum of clinical manifestations and complications. Confirmation of the diagnosis is based upon an elevated sweat sodium concentration or chloride concentration accompanied by one or more of the following: the presence of chronic obstructive pulmonary disease, insufficiency of exocrine pancreatic function, meconium ileus, or a positive family history. The quantitative pilocarpine iontophoresis procedure for collection of sweat content must be utilized. Two methods are acceptable: the "Procedure for the Quantitative Iontophoretic Sweat Test for Cystic Fibrosis" published by the Cystic Fibrosis Foundation and contained in, "A Test for Concentration of Electrolytes in Sweat in Cystic Fibrosis of the Pancreas Utilizing Pilocarpine Iontophoresis," Gibson, I.E., and Cooke, R..E., Pediatrics, Vol. 23:545, 1959; or the "Wescor Macroduct System." To establish the diagnosis of cystic fibrosis, the sweat sodium or chloride content must be analyzed quantitatively using an acceptable laboratory technique. Another diagnostic test is the "CF gene mutation analysis" for homozygosity of the cystic fibrosis gene. The pulmonary manifestations of this disorder should be evaluated under 3.04. The nonpulmonary aspects of cystic fibrosis should be evaluated under the digestive body system (5.00). Because cystic fibrosis may involve the respiratory and digestive body systems, the combined effects of the involvement of these body systems must be considered in case adjudication.

E. *Documentation of pulmonary function testing.* The results of spirometry that are used for adjudication under paragraphs A and B of 3.02 and paragraph A of 3.04 should be expressed in liters (L), body temperature and pressure saturated with water vapor (BTPS). The reported one-second forced expiratory volume (FEV_1) and forced vital capacity (FVC) should represent the largest of at least three satisfactory forced expiratory maneuvers. Two of the satisfactory

spirograms should be reproducible for both pre-bronchodilator tests and, if indicated, post-bronchodilator tests. A value is considered reproducible if it does not differ from the largest value by more than 5 percent or 0.1 L, whichever is greater. The highest values of the FEV_1 and FVC, whether from the same or different tracings, should be used to assess the severity of the respiratory impairment. Peak flow should be achieved early in expiration, and the spirogram should have a smooth contour with gradually decreasing flow throughout expiration. The zero time for measurement of the FEV_1 and FVC, if not distinct, should be derived by linear back-extrapolation of peak flow to zero volume. A spirogram is satisfactory for measurement of the FEV_1 if the expiratory volume at the back-extrapolated zero time is less than 5 percent of the FVC or 0.1 L, whichever is greater. The spirogram is satisfactory for measurement of the FVC if maximal expiratory effort continues for at least 6 seconds, or if there is a plateau in the volume-time curve with no detectable change in expired volume (VE) during the last 2 seconds of maximal expiratory effort.

Spirometry should be repeated after administration of an aerosolized bronchodilator under supervision of the testing personnel if the pre-bronchodilator FEV_1 value is less than 70 percent of the predicted normal value. Pulmonary function studies should not be performed unless the clinical status is stable (e.g., the individual is not having an asthmatic attack or suffering from an acute respiratory infection or other acute illness.). Wheezing is common in asthma, chronic bronchitis, or chronic obstructive pulmonary disease and does not preclude testing. The effect of the administered bronchodilator in relieving bronchospasm and improving ventilatory function is assessed by spirometry. If a bronchodilator is not administered, the reason should be clearly stated in the report. Pulmonary function studies performed to assess airflow obstruction without testing after bronchodilators cannot be used to assess levels of impairment in the range that prevents any gainful work activity, unless the use of bronchodilators is contraindicated. Post-bronchodilator testing should be performed 10 minutes after bronchodilator administration. The dose and name of the bronchodilator administered should be specified. The values in paragraphs A and B of 3.02 must only be used as criteria for the level of ventilatory impairment that exists during the individual's most stable state of health (i.e., any period in time except during or shortly after an exacerbation).

The appropriately labeled spirometric tracing, showing the claimant's name, date of testing, distance per second on the abscissa and the distance per liter (L) on the ordinate, must be incorporated into the file. The manufacturer and model number of the device used to measure and record the spirogram should be stated. The testing device must accurately measure both time and volume, the latter to within 1 percent of a 3 L calibrating volume. If the spirogram was generated by any means other than direct pen linkage to a mechanical displacement-type spirometer, the spirometric tracing must show a recorded calibration of volume units using a mechanical volume input such as a 3 L syringe.

If the spirometer directly measures flow, and volume is derived by electronic integration, the linearity of the device must be documented by recording volume calibrations at three different flow rates of approximately 30 L/min (3 L/6 sec), 60 L/min (3 L/3 sec), and 180 L/min (3 L/sec). The volume calibrations should agree to within 1 percent of a 3 L calibrating volume. The proximity of the

flow sensor to the individual should be noted, and it should be stated whether or not a BTPS correction factor was used for the calibration recordings and for the individual's actual spirograms.

The spirogram must be recorded at a speed of at least 20 mm/sec, and the recording device must provide a volume excursion of at least 10 mm/L. If reproductions of the original spirometric tracings are submitted, they must be legible and have a time scale of at least 20 mm/sec and a volume scale of at least 10 mm/L to permit independent measurements. Calculation of FEV_1 from a flow-volume tracing is not acceptable, i.e., the spirogram and calibrations must be presented in a volume-time format at a speed of at least 20 mm/sec and a volume excursion of at least 10 mm/L to permit independent evaluation.

A statement should be made in the pulmonary function test report of the individual's ability to understand directions as well as his or her effort and cooperation in performing the pulmonary function tests.

The pulmonary function tables in 3.02 and 3.04 are based on measurement of standing height without shoes. If an individual has marked spinal deformities (e.g., kyphoscoliosis), the measured span between the fingertips with the upper extremities abducted 90 degrees should be substituted for height when this measurement is greater than the standing height without shoes.

F. Documentation of Chronic Impairment of Gas Exchange.

1. *Diffusing capacity of the lungs for carbon monoxide (DLCO).* A diffusing capacity of the lungs for carbon monoxide study should be purchased in cases in which there is documentation of chronic pulmonary disease, but the existing evidence, including properly performed spirometry, is not adequate to establish the level of functional impairment. Before purchasing DLCO measurements, the medical history, physical examination, reports of chest x-ray or other appropriate imaging techniques, and spirometric test results must be obtained and reviewed because favorable decisions can often be made based on available evidence without the need for DLCO studies. Purchase of a DLCO study may be appropriate when there is a question of whether an impairment meets or is equivalent in severity to a listing, and the claim cannot otherwise be favorably decided.

The DLCO should be measured by the single breath technique with the individual relaxed and seated. At sea level, the inspired gas mixture should contain approximately 0.3 percent carbon monoxide (C0), 10 percent helium (He), 21 percent oxygen (O_2), and the balance nitrogen. At altitudes above sea level, the inspired O_2 concentration may be raised to provide an inspired 0_2 tension of approximately 150 mm Hg. Alternatively, the sea level mixture may be employed at altitude and the measured DLCO corrected for ambient barometric pressure. Helium may be replaced by another inert gas at an appropriate concentration. The inspired volume (VI) during the DLCO maneuver should be at least 90 percent of the previously determined vital capacity (VC). The inspiratory time for the VI should be less than 2 seconds, and the breath-hold time should be between 9 and 11 seconds. The washout volume should be between 0.75 and 1.00 L, unless the VC is less than 2 L. In this case, the washout volume may be reduced to 0.50 L; any such change

should be noted in the report. The alveolar sample volume should be between 0.5 and 1.0 L and be collected in less than 3 seconds. At least 4 minutes should be allowed for gas washout between repeat studies.

A DLCO should be reported in units of ml CO, standard temperature, pressure, dry (STPD)/min/mm Hg uncorrected for hemoglobin concentration and be based on a single-breath alveolar volume determination. Abnormal hemoglobin or hematocrit values, and/or carboxyhemoglobin levels should be reported along with diffusing capacity.

The DLCO value used for adjudication should represent the mean of at least two acceptable measurements, as defined above. In addition, two acceptable tests should be within 10 percent of each other or 3 ml CO(STPD)/min/mm Hg, whichever is larger. The percent difference should be calculated as 100 x (test 1 - test 2)/average DLCO.

The ability of the individual to follow directions and perform the test properly should be described in the written report. The report should include tracings of the VI, breath-hold maneuver, and VE appropriately labeled with the name of the individual and the date of the test. The time axis should be at least 20 mm/sec and the volume axis at least 10 mm/L. The percentage concentrations of inspired O2, and inspired and expired CO and He for each of the maneuvers should be provided, and the algorithm used to calculate test results noted. Sufficient data must be provided to permit independent calculation of results (and, if necessary, calculation of corrections for anemia and/or carboxyhemoglobin).

2. *Arterial blood gas studies (ABGS).* An ABGS performed at rest (while breathing room air, awake and sitting or standing) or during exercise should be analyzed in a laboratory certified by a State or Federal agency. If the laboratory is not certified, it must submit evidence of participation in a national proficiency testing program as well as acceptable quality control at the time of testing. The report should include the altitude of the facility and the barometric pressure on the date of analysis.

Purchase of resting ABGS may be appropriate when there is a question of whether an impairment meets or is equivalent in severity to a listing, and the claim cannot otherwise be favorably decided. If the results of a DLCO study are greater than 40 percent of predicted normal but less than 60 percent of predicted normal, purchase of resting ABGS should be considered. Before purchasing resting ABGS, a program physician, preferably one experienced in the care of patients with pulmonary disease, must review all clinical and laboratory data short of this procedure, including spirometry, to determine whether obtaining the test would present a significant risk to the individual.

3. *Exercise testing*. Exercise testing with measurement of arterial blood gases during exercise may be appropriate in cases in which there is documentation of chronic pulmonary disease, but full development, short of exercise testing, is not adequate to establish if the impairment meets or is equivalent in severity to a listing, and the claim cannot otherwise be favorably decided. In this context, "full development" means that results from spirometry and measurement of DLCO and resting ABGS have been obtained from treating sources or through purchase. Exercise arterial blood gas measurements will be required

infrequently and should be purchased only after careful review of the medical history, physical examination, chest x-ray or other appropriate imaging techniques, spirometry, DLCO, electrocardiogram (ECG), hematocrit or hemoglobin, and resting blood gas results by a program physician, preferably one experienced in the care of patients with pulmonary disease, to determine whether obtaining the test would present a significant risk to the individual. Oximetry and capillary blood gas analysis are not acceptable substitutes for the measurement of arterial blood gases. Arterial blood gas samples obtained after the completion of exercise are not acceptable for establishing an individual's functional capacity.

Generally, individuals with a DLCO greater than 60 percent of predicted normal would not be considered for exercise testing with measurement of blood gas studies. The exercise test facility must be provided with the claimant's clinical records, reports of chest x-ray or other appropriate imaging techniques, and any spirometry, DLCO, and resting blood gas results obtained as evidence of record. The testing facility must determine whether exercise testing presents a significant risk to the individual; if it does, the reason for not performing the test must be reported in writing.

4. *Methodology.* Individuals considered for exercise testing first should have resting arterial blood partial pressure of oxygen (PO_2), resting arterial blood partial pressure of carbon dioxide (PCO_2) and negative log of hydrogen ion concentration (pH) determinations by the testing facility. The sample should be obtained in either the sitting or standing position. The individual should then perform exercise under steady state conditions, preferably on treadmill, breathing room air, for a period of 4 to 6 minutes at a speed and grade providing an Oxygen consumption of approximately 17.5 ml/kg/min (5 METs). If a bicycle ergometer is used, an exercise equivalent of 5 METs (e.g., 450 kpm./min., or 75 watts for a 176 pound (80 kilogram) person) should be used. If the individual is able to complete this level of exercise without achieving listing-level hypoxemia, then he or she should be exercised at higher workloads to determine exercise capacity. A warm-up period of treadmill walking or cycling may be performed to acquaint the individual with the exercise procedure. If during the warm-up period the individual cannot achieve an exercise level of 5 METs, a lower workload may be selected in keeping with the estimate of exercise capacity. The individual should be monitored by ECG throughout the exercise and in the immediate post-exercise period. Blood pressure and an ECG should be recorded during each minute of exercise. During the final 2 minutes of a specific level of steady state exercise, an arterial blood sample should be drawn and analyzed for oxygen pressure (or tension) (PO_2), carbon dioxide pressure (or tension) (PCO_2), and pH. At the discretion of the testing facility, the sample may be obtained either from an indwelling arterial catheter or by direct arterial puncture. If possible, in order to evaluate exercise capacity more accurately, a test site should be selected that has the capability to measure minute ventilation, O_2 consumption and carbon dioxide (CO_2) production. If the claimant fails to complete 4 to 6 minutes of steady state exercise, the testing laboratory should comment on the reason and report the actual duration and levels of exercise performed. This comment is necessary to determine if the individual's test performance was limited by lack of effort or

other impairment (e.g., cardiac, peripheral vascular, musculoskeletal, neurological).

The exercise test report should contain representative ECG strips taken before, during and after exercise; resting and exercise arterial blood gas values; treadmill speed and grade settings, or, if a bicycle ergometer was used, exercise levels expressed in watts or kpm/min; and the duration of exercise. Body weight also should be recorded. If measured, O_2 consumption (STPD), minute ventilation (BTPS), and CO_2 production (STPD) also should be reported. The altitude of the test site, its normal range of blood gas values, and the barometric pressure on the test date must be noted.

G. *Chronic cor pulmonale and pulmonary vascular disease.* The establishment of an impairment attributable to irreversible cor pulmonale secondary to chronic pulmonary hypertension requires documentation by signs and laboratory findings of right ventricular overload or failure (e.g., an early diastolic right-sided gallop on auscultation, neck vein distension, hepatomegaly, peripheral edema, right ventricular outflow tract enlargement on x-ray or other appropriate imaging techniques, right ventricular hypertrophy on ECG, and increased pulmonary artery pressure measured by right heart catheterization available from treating sources). Cardiac catheterization will not be purchased. Because hypoxemia may accompany heart failure and is also a cause of pulmonary hypertension, and may be associated with hypoventilation and respiratory acidosis, arterial blood gases may demonstrate hypoxemia (decreased PO_2), CO_2 retention (increased PCO_2), and acidosis (decreased pH). Polycythemia with an elevated red blood cell count and hematocrit may be found in the presence of chronic hypoxemia.

P-pulmonale on the ECG does not establish chronic pulmonary hypertension or chronic cor pulmonale. Evidence of florid right heart failure need not be present at the time of adjudication for a listing (e.g., 3.09) to be satisfied, but the medical evidence of record should establish that cor pulmonale is chronic and irreversible.

H. *Sleep-related breathing disorders.* Sleep-related breathing disorders (sleep apneas) are caused by periodic cessation of respiration associated with hypoxemia and frequent arousals from sleep. Although many individuals with one of these disorders will respond to prescribed treatment, in some, the disturbed sleep pattern and associated chronic nocturnal hypoxemia cause daytime sleepiness with chronic pulmonary hypertension and/or disturbances in cognitive function. Because daytime sleepiness can affect memory, orientation, and personality, a longitudinal treatment record may be needed to evaluate mental functioning. Not all individuals with sleep apnea develop a functional impairment that affects work activity. When any gainful work is precluded, the physiologic basis for the impairment may be chronic cor pulmonale. Chronic hypoxemia due to episodic apnea may cause pulmonary hypertension (see 3.00G and 3.09). Daytime somnolence may be associated with disturbance in cognitive vigilance. Impairment of cognitive function may be evaluated under organic mental disorders (12.02). If the disorder is associated with gross obesity, it should be evaluated under the applicable obesity listing.

3.01 CATEGORY OF IMPAIRMENTS, RESPIRATORY SYSTEM

3.02 *Chronic Pulmonary insufficiency*

A. Chronic obstructive pulmonary disease due to any cause, with the FEV_1 equal to or less than the values specified in table I corresponding to the person's height without shoes. (In cases of marked spinal deformity, see 3.00E.);

Table I

Height without shoes (centimeters)	Height without shoes (inches)	FEV_1 Equal to or less than (L, BTPS)
154 or less	60 or less	1.05
155–160	61–63	1.15
161–165	T64-65	1.25
166–170	66–67	1.35
171–175	68–69	1.45
176–180	70–71	1.55
181 or more	72 or more	1.65

Or

B. Chronic restrictive ventilatory disease, due to any cause, with the FVC equal to or less than the values specified in Table II corresponding to the person's height without shoes. (In cases of marked spinal deformity, see 3.00E.);

Table II

Height without shoes (centimeters)	Height without shoes (inches)	FVC Equal to or less than (L, BTPS)
154 or less	60 or less	1.25
155–160	61–63	1.35
161–165	T64-65	1.45
166–170	66–67	1.55
171–175	68–69	1.65
176–180	70–71	1.75
181 or more	72 or more	1.85

Or

C. Chronic impairment of gas exchange due to clinically documented pulmonary disease. With:

1. Single breath DLCO (see 3.00F1) less than 10.5 ml/min/mm Hg or less than 40 percent of the predicted normal value. (Predicted values must either be based on data obtained at the test site or published values from a laboratory using the same technique as the test site. The source of the predicted values should be reported. If they are not published, they should be submitted in the form of a table or nomogram); or

2. Arterial blood gas values of PO_2 and simultaneously determined PCO_2 measured while at rest (breathing room air, awake and sitting or standing) in a clinically stable condition on at least two occasions, three or more weeks apart within a 6-month period, equal to or less then the values specified in the applicable table III-A or III-B or III-C:

Table III-A

(Applicable at test sites less than 3,000 feet above sea level)

Arterial PCO_2 (mm. Hg.) and	Arterial PO_2 Equal to or Less than (mm. Hg.)	
30 or below	65	
31	64	
32	63	
33	62R34	61
35	60	
36	59	
37	58	
38	57	
39	56	
40 or above	55	

Table III-B

(Applicable at test sites 3,000 through 6,000 feet above sea level)

Arterial PCO_2 (mm. Hg.) and	Arterial PO_2 equal to or less than (mm. Hg.)	
30 or below	60	
31	59	
32	58	
33	57R34	56
35	55	
36	54	
37	53	
38	52	
39	51	
40 or above	50	

Table III-C

(Applicable at test sites over 6,000 feet above sea level)

Arterial PCO_2 (mm. Hg.) and	Arterial PO_2 equal to or less than (mm. Hg.)
30 or below	55
31	54
32	53
33	52R34
35	50
36	49
37	48
38	47
39	46
40 or above	45

51

Or

3. Arterial blood gas values of PO_2 and simultaneously determined PCO_2 during steady state exercise breathing room air (level of exercise equivalent to or less than 17.5 ml O_2 consumption/kg/min or 5 METs) equal to or less than the values specified in the applicable table III-A or III-B or III-C in 3.02 C2.

3.03 *Asthma.* With:

A. Chronic asthmatic bronchitis. Evaluate under the criteria for chronic obstructive pulmonary disease in 3.02A;

Or

B. Attacks (as defined in 3.00C), in spite of prescribed treatment and requiring physician intervention, occurring at least once every 2 months or at least six times a year. Each in-patient hospitalization for longer than 24 hours for control of asthma counts as two attacks, and an evaluation period of at least 12 consecutive months must be used to determine the frequency of attacks.

3.04 *Cystic fibrosis*. With:

A. An FEV_1 equal to or less than the appropriate value specified in table IV corresponding to the individual's height without shoes. (In cases of marked spinal deformity, see. 3.00E.);

Or

B. Episodes of bronchitis or pneumonia or hemoptysis (more than blood-streaked sputum) or respiratory failure (documented according to 3.00C), requiring physician intervention, occurring at least once every 2 months or at least six times a year. Each inpatient hospitalization for longer than 24 hours for treatment counts as two episodes, and an evaluation period of at least 12 consecutive months must be used to determine the frequency of episodes;

Or

C. Persistent pulmonary infection accompanied by superimposed, recurrent, symptomatic episodes of increased bacterial infection occurring at least once every 6 months and requiring intravenous or nebulization antimicrobial therapy.

Table IV

(Applicable only for evaluation under 3.04A - cystic fibrosis)

Height without shoes (centimeters)	Height without shoes (inches)	FEV_1 Equal to or less than (L, BTPS)
154 or less	60 or less	1.45
155–159	61–62	1.55
160–164	63–64	1.65
165–169	65–66	1.75
170–174	67–68	1.85
175–179	69–70	1.95
180 or more	71 or more	2.05

3.06 *Pneumoconiosis* (demonstrated by appropriate imaging techniques). Evaluate under the appropriate criteria in 3.02.

3.07 *Bronchiectasis* (demonstrated by appropriate imaging techniques). With:

A. Impairment of pulmonary function due to extensive disease. Evaluate under the appropriate criteria in 3.02;

Or

B. Episodes of bronchitis or pneumonia or hemoptysis (more than blood-streaked sputum) or respiratory failure (documented according to 3.00C), requiring physician intervention, occurring at least once every 2 months or at least six times a year. Each in-patient hospitalization for longer than 24 hours for treatment counts as two episodes, and an evaluation of at least 12 consecutive months must be used to determine the frequency of episodes.

3.08 *Mycobacterial, mycotic, and other chronic persistent infections of the lung.* (see 3.00B). Evaluate under the appropriate criteria in 3.02.

3.09 *Cor pulmonale secondary to chronic pulmonary vascular hypertension.* Clinical evidence of cor pulmonale (documented according to 3.00G) with:

A. Mean pulmonary artery pressure greater than 40 mm Hg:

Or

B. Arterial hypoxemia. Evaluate under the criteria in 3.02 C2;

Or

C. Evaluate under the applicable criteria in 4.02.

3.10 *Sleep-related breathing disorders.* Evaluate under 3.09 (chronic cor pulmonale), 9.09 (obesity), or 12.02 (organic mental disorders).

4.00 CARDIOVASCULAR SYSTEM

A. *Introduction.* The listings in this section describe impairments resulting from cardiovascular disease based on symptoms, physical signs, laboratory test abnormalities, and response to a regimen of therapy prescribed by a treating source. A longitudinal clinical record covering a period of not less than 3 months of observations and therapy is usually necessary for the assessment of severity and expected duration of cardiovascular impairment, unless the claim can be decided favorably on the basis of the current evidence. All relevant evidence must be considered in assessing disability.

Many individuals, especially those who have listing-level impairments, will have received the benefit of medically prescribed treatment. Whenever there is evidence of such treatment, the longitudinal clinical record must include a description of the therapy prescribed by the treating source and response, in addition to information about the nature and severity of the impairment. It is important to document any prescribed therapy and response because this medical management may have improved the individual's functional status. The longitudinal record should provide information regarding functional recovery, if any.

Some individuals will not have received ongoing treatment or have an ongoing relationship with the medical community despite the existence of a severe impairment(s). Unless the claim can be decided favorably on the basis of the current evidence, a longitudinal record is still important because it will provide information about such things as the ongoing medical severity of the impairment, the degree of recovery from cardiac insult, the level of the individual's functioning, and the frequency, severity, and duration of symptoms. Also, several listings include a requirement for continuing signs and symptoms despite a regimen of prescribed treatment. Even though an individual who does not receive treatment may not be able to show an impairment that meets the criteria of these listings, the individual may have an impairment(s) equivalent in severity to one of the listed impairments or be disabled because of a limited residual functional capacity.

Indeed, it must be remembered that these listings are only examples of common cardiovascular disorders that are severe enough to prevent a person from engaging in gainful activity. Therefore, in any case in which an individual has a medically determinable impairment that is not listed, or a combination of impairments no one of which meets a listing, we will make a medical equivalence determination. Individuals who have an impairment(s) with a level of severity which does not meet or equal the criteria of the cardiovascular listings may or may not have the residual functional capacity (RFC) which would enable them to engage in substantial gainful activity. Evaluation of the

impairment(s) of these individuals should proceed through the final steps of the sequential evaluation process (or, as appropriate, the steps in the medical improvement review standard).

B. *Cardiovascular impairment* results from one or more of four consequences of heart disease:

1. Chronic heart failure or ventricular dysfunction.

2. Discomfort or pain due to myocardial ischemia, with or without necrosis of heart muscle.

3. Syncope, or near syncope, due to inadequate cerebral perfusion from any cardiac cause such as obstruction of flow or disturbance in rhythm or conduction resulting in inadequate cardiac output.

4. Central cyanosis due to right-to-left shunt, arterial desaturation, or pulmonary vascular disease.

Impairment from diseases of arteries and veins may result from disorders of the vasculature in the central nervous system (11.04A, B), eyes (2.02-2.04), kidney (6.02), and other organs.

C. *Documentation.* Each individual's file must include sufficiently detailed reports on history, physical examinations, laboratory studies, and any prescribed therapy and response to allow an independent reviewer to assess the severity and duration of the cardiovascular impairment.

1. Electrocardiography.

a. An original or legible copy of the 12-lead electrocardiogram (ECG) obtained at rest must be submitted, appropriately dated and labeled, with the standardization inscribed on the tracing. Alteration in standardization of specific leads (such as to accommodate large QRS amplitudes) must be identified on those leads.

(1) Detailed descriptions or computer-averaged signals without original or legible copies of the ECG as described in subsection 4.00C1a are not acceptable.

(2) The effects of drugs or electrolyte abnormalities must be considered as possible noncoronary causes of ECG abnormalities of ventricular repolarization, i.e., those involving the ST segment and T wave. If available, the predrug (especially digitalis glycoside) ECG should be submitted.

(3) The term "ischemic" is used in 4.04A to describe an abnormal ST segment deviation. Nonspecific repolarization abnormalities should not be confused with "ischemic" changes.

b. ECGs obtained in conjunction with treadmill, bicycle, or arm exercise tests should meet the following specifications:

(1) ECGs must include the original calibrated ECG tracings or a legible copy.

(2) A 12-lead baseline ECG must be recorded in the upright position before exercise.

(3) A 12-lead ECG should be recorded at the end of each minute of exercise, including at the time the ST segment abnormalities reach or exceed the

criteria for abnormality described in 4.04A or the individual experiences chest discomfort or other abnormalities, and also when the exercise test is terminated.

(4) If ECG documentation of the effects of hyperventilation is obtained, the exercise test should be deferred for at least 10 minutes because metabolic changes of hyperventilation may alter the physiologic and ECG response to exercise.

(5) Post-exercise ECGs should be recorded using a generally accepted protocol consistent with the prevailing state of medical knowledge and clinical practice.

(6) All resting, exercise, and recovery ECG strips must have a standardization inscribed on the tracing. The ECG strips should be labeled to indicate the times recorded and the relationship to the stage of the exercise protocol. The speed and grade (treadmill test) or work rate (bicycle or arm ergometric test) should be recorded. The highest level of exercise achieved, blood pressure levels during testing, and the reason(s) for terminating the test (including limiting signs or symptoms) must be recorded.

2. Purchasing exercise tests.

a. It is well recognized by medical experts that exercise testing is the best tool currently available for estimating maximal aerobic capacity in individuals with cardiovascular impairments. Purchase of an exercise test may be appropriate when there is a question whether an impairment meets or is equivalent in severity to one of the listings, or when there is insufficient evidence in the record to evaluate aerobic capacity, and the claim cannot otherwise be favorably decided. Before purchasing an exercise test, a program physician, preferably one with experience in the care of patients with cardiovascular disease, must review the pertinent history, physical examinations, and laboratory tests to determine whether obtaining the test would present a significant risk to the individual (see 4.00C2c). Purchase may be indicated when there is no significant risk to exercise testing and there is no timely test of record. An exercise test is generally considered timely for 12 months after the date performed, provided there has been no change in clinical status that may alter the severity of the cardiac impairment.

b. Methodology

(1)When an exercise test is purchased, it should be a “sign- or symptom-limited” test characterized by a progressive multistage regimen. A purchased exercise test must be performed using a generally accepted protocol consistent with the prevailing state of medical knowledge and clinical practice. A description of the protocol that was followed must be provided and the test must meet the requirements of 4.00C1b and this section. A pre-exercise posthyperventilation tracing may be essential for the proper evaluation of an “abnormal” test in certain circumstances, such as in women with evidence of mitral valve prolapse.

(2) The exercise test should be paced to the capabilities of the individual and be supervised by a physician. With a treadmill test, the speed, grade (incline) and duration of exercise must be recorded for each exercise test stage performed.

Other exercise test protocols or techniques that are used should utilize similar workloads.

(3) Levels of exercise should be described in terms of workload and duration of each stage, e.g., treadmill speed and grade, or bicycle ergometer work rate in kpm/min or watts.

(4) Normally, systolic blood pressure and heart rate increase gradually with exercise. A decrease in systolic blood pressure during exercise below the usual resting level is often associated with ischemia-induced left ventricular dysfunction resulting in decreased cardiac output. Some individuals (because of deconditioning or apprehension) with increased sympathetic responses may increase their systolic blood pressure and heart rate above their usual resting level just before and early into exercise. This occurrence may limit the ability to assess the significance of an early decrease in systolic blood pressure and heart rate if exercise is discontinued shortly after initiation. In addition, isolated systolic hypertension may be a manifestation of arteriosclerosis.

(5) The exercise laboratory's physical environment, staffing, and equipment should meet the generally accepted standards for adult exercise test laboratories.

c. Risk factors in exercise testing.

The following are examples of situations in which exercise testing will not be purchased: unstable progressive angina pectoris, a history of acute myocardial infarction within the past 3 months, New York Heart Association (NYHA) class IV heart failure, cardiac drug toxicity, uncontrolled serious arrhythmia (including uncontrolled atrial fibrillation, Mobitz II, and third-degree block), Wolff-Parkinson-White syndrome, uncontrolled severe systemic arterial hypertension, marked pulmonary hypertension, unrepaired aortic dissection, left main stenosis of 50 percent or greater, marked aortic stenosis, chronic or dissecting aortic aneurysm, recent pulmonary embolism, hypertrophic cardiomyopathy, limiting neurological or musculoskeletal impairments, or an acute illness. In addition, an exercise test should not be purchased for individuals for whom the performance of the test is considered to constitute a significant risk by a program physician, preferably one experienced in the care of patients with cardiovascular disease, even in the absence of any of the above risk factors. In defining risk, the program physician, in accordance with the regulations and other instructions on consultative examinations, will generally give great weight to the treating physicians' opinions and will generally not override them. In the rare situation in which the program physician does override the treating source's opinion, a written rationale must be prepared documenting the reasons for overriding the opinion.

d. In order to permit maximal, attainable restoration of functional capacity, exercise testing should not be purchased until 3 months after an acute myocardial infarction, surgical myocardial revascularization, or other open-heart surgical procedures. Purchase of an exercise test should also be deferred for 3 months after percutaneous transluminal coronary angioplasty because restenosis with ischemic symptoms may occur within a few months of angioplasty (see 4.00D). Also, individuals who have had a period of bedrest or inactivity (e.g., 2 weeks) that results in a reversible deconditioned state may do poorly if exercise testing is performed at that time.

e. Evaluation.

(1) Exercise testing is evaluated on the basis of the work level at which the test becomes abnormal, as documented by onset of signs and symptoms and any ECG abnormalities listed in 4.04A. The ability or inability to complete an exercise test is not, by itself, evidence that a person is free from ischemic heart disease. The results of an exercise test must be considered in the context of all of the other evidence in the individual's case record. If the individual is under the care of a treating physician for a cardiac impairment, and this physician has not performed an exercise test and there are no reported significant risks to testing (see 4.00C2c), a statement should be requested from the treating physician explaining why it was not done or should not be done before deciding whether an exercise test should be purchased. In those rare situations in which the treating source's opinion is overridden, follow 4.00C2c. If there is no treating physician, the program physician will be responsible for assessing the risk to exercise testing.

(2) Limitations to exercise test interpretation include the presence of noncoronary or nonischemic factors that may influence the hemodynamic and ECG response to exercise, such as hypokalemia or other electrolyte abnormality, hyperventilation, vasoregulatory deconditioning, prolonged periods of physical inactivity (e.g., 2 weeks of bedrest), significant anemia, left bundle branch block pattern on the ECG (and other conduction abnormalities that do not preclude the purchase of exercise testing), and other heart diseases or abnormalities (particularly valvular heart disease). Digitalis glycosides may cause ST segment abnormalities at rest, during, and after exercise. Digitalis or other drug-related ST segment displacement, present at rest, may become accentuated with exercise and make ECG interpretation difficult, but such drugs do not invalidate an otherwise normal exercise test. Diuretic-induced hypokalemia and left ventricular hypertrophy may also be associated with repolarization changes and behave similarly. Finally, treatment with beta blockers slows the heart rate more at near-maximal exertion than at rest; this limits apparent chronotropic capacity.

3. Other studies.

Information from two-dimensional and Doppler echocardiographic studies of ventricular size and function as well as radionuclide (thallium^{201}) myocardial "perfusion" or radionuclide (technetium 99m) ventriculograms (RVG or MUGA) may be useful. These techniques can provide a reliable estimate of ejection fraction. In selected cases, these tests may be purchased after a medical history and physical examination, report of chest x-rays, ECGs, and other appropriate tests have been evaluated, preferably by a program physician with experience in the care of patients with cardiovascular disease. Purchase should be considered when other information available is not adequate to assess whether the individual may have severe ventricular dysfunction or myocardial ischemia and there is no significant risk involved (follow 4.00C2a guides), and the claim cannot be favorably decided on any other basis.

Exercise testing with measurement of maximal oxygen uptake ($V0_2$) provides an accurate determination of aerobic capacity. An exercise test without measurement of oxygen uptake provides an estimate of aerobic capacity. When

the results of tests with measurement of oxygen uptake are available, every reasonable effort should be made to obtain them.

The recording of properly calibrated ambulatory ECGs for analysis of ST segment signals with a concomitantly recorded symptom and treatment log may permit more adequate evaluation of chest discomfort during activities of daily living, but the significance of these data for disability evaluation has not been established in the absence of symptoms (e.g., silent ischemia). This information (including selected segments of both the ECG recording and summary report of the patient diary) may be submitted for the record.

4. **Cardiac catheterization** will not be purchased by the Social Security Administration.

a. Coronary arteriography

If results of such testing are available, the report should be obtained and considered as to the quality and type of data provided and its relevance to the evaluation of the impairment. A copy of the report of the cardiac catheterization and ancillary studies should also be obtained. The report should provide information citing the method of assessing coronary arterial lumen diameter and the nature and location of obstructive lesions. Drug treatment at baseline and during the procedure should be reported. Coronary artery spasm induced by intracoronary catheterization is not to be considered evidence of ischemic disease. Some individuals with significant coronary atherosclerotic obstruction have collateral vessels that supply the myocardium distal to the arterial obstruction so that there is no evidence of myocardial damage or ischemia, even with exercise. When available, quantitative computer measurements and analyses should be considered in the interpretation of severity of stenotic lesions.

b. Left ventriculography (by angiography).

The report should describe the wall motion of the myocardium with regard to any areas of hypokinesis, akinesis, or dyskinesis, and the overall contraction of the ventricle as measured by the ejection fraction. Measurement of chamber volumes and pressures may be useful. When available, quantitative computer analysis provides precise measurement of segmental left ventricular wall thickness and motion. There is often a poor correlation between left ventricular function at rest and functional capacity for physical activity.

D. Treatment and relationship to functional status.

1. In general, conclusions about the severity of a cardiovascular impairment cannot be made on the basis of type of treatment rendered or anticipated. The overall clinical and laboratory evidence, including the treatment plan(s) or results, should be persuasive that a listing-level impairment exists. The amount of function restored and the time required for improvement after treatment (medical, surgical, or a prescribed program of progressive physical activity) vary with the nature and extent of the disorder, the type of treatment, and other factors. Depending upon the timing of this treatment in relation to the alleged onset date of disability, impairment evaluation may need to be deferred for a period of up to 3 months from the date of treatment to permit consideration of

treatment effects. Evaluation should not be deferred if the claim can be favorably decided based upon the available evidence.

2. The usual time after myocardial infarction, valvular and/or revascularization surgery for adequate assessment of the results of treatment is considered to be 3 months. If an exercise test is performed by a treating source within a week or two after angioplasty, and there is no significant change in clinical status during the 3-month period after the angioplasty that would invalidate the implications of the exercise test results, the exercise test results may be used to reflect functional capacity during the period in question. However, if the test was done immediately following an acute myocardial infarction or during a period of protracted inactivity, the results should not be projected to 3 months even if there is no change in clinical status.

3. An individual who has undergone cardiac transplantation will be considered under a disability for 1 year following the surgery because, during the first year, there is a greater likelihood of rejection of the organ and recurrent infection. After the first year posttransplantation, continuing disability evaluation will be based upon residual impairment as shown by symptoms, signs, and laboratory findings. Absence of symptoms, signs, and laboratory findings indicative of cardiac dysfunction will be included in the consideration of whether medical improvement (as defined in §§404.1579(b)(1) and (c)(1), 404.1594 (b)(1) and (c)(1), or 416.994 (b)(1)(i) and (b)(2)(i), as appropriate) has occurred.

E. Clinical syndromes.

1. Chronic heart failure (ventricular dysfunction) is considered in these listings as one category whatever its etiology, i.e., atherosclerotic, hypertensive, rheumatic, pulmonary, congenital or other organic heart disease. Chronic heart failure may manifest itself by:

a. Pulmonary or systemic congestion, or both; or

b. Symptoms of limited cardiac output, such as weakness, fatigue, or intolerance of physical activity.

For the purpose of 4.02A, pulmonary and systemic congestion are not considered to have been established unless there is or has been evidence of fluid retention, such as hepatomegaly or ascites, or peripheral or pulmonary edema of cardiac origin. The findings of fluid retention need not be present at the time of adjudication because congestion may be controlled with medication. Chronic heart failure due to limited cardiac output is not considered to have been established for the purpose of 4.02B unless symptoms occur with ordinary daily activities, i.e., activity restriction as manifested by a need to decrease activity or pace, or to rest intermittently, and are associated with one or more physical signs or abnormal laboratory studies listed in 4.02B. These studies include exercise testing with ECG and blood pressure recording and/or appropriate imaging techniques, such as two-dimensional echocardiography or radionuclide or contrast ventriculography. The exercise criteria are outlined in 4.02B1. In addition, other abnormal symptoms, signs, or laboratory test results that lend credence to the impression of ventricular dysfunction should be considered.

2. For the purposes of 4.03, hypertensive cardiovascular disease is evaluated by reference to the specific organ system involved (heart, brain, kidneys, or eyes). The presence of organic impairment must be established by appropriate physical signs and laboratory test abnormalities as specified in 4.02 or 4.04, or for the body system involved.

3. Ischemic (coronary) heart disease may result in an impairment due to myocardial ischemia and/or ventricular dysfunction or infarction. For the purposes of 4.04, the clinical determination that discomfort of myocardial ischemic origin (angina pectoris) is present must be supported by objective evidence as described under 4.00C1, 2, 3, or 4.

a. Discomfort of myocardial ischemic origin (angina pectoris) is discomfort that is precipitated by effort and/or emotion and promptly relieved by sublingual nitroglycerin, other rapidly acting nitrates, or rest. Typically the discomfort is located in the chest (usually substernal) and described as crushing, squeezing, burning, aching, or oppressive. Sharp, sticking, or cramping discomfort is considered less common or atypical. Discomfort occurring with activity or emotion should be described specifically as to timing and usual inciting factors (type and intensity), character, location, radiation, duration, and response to nitrate therapy or rest.

b. So-called anginal equivalent may be localized to the neck, jaw(s), or hand(s) and has the same precipitating and relieving factors as typical chest discomfort. Isolated shortness of breath (dyspnea) is not considered an anginal equivalent for purposes of adjudication.

c. Variant angina of the Prinzmetal type, i.e., rest angina with transitory ST segment elevation on ECG, may have the same significance as typical angina, described in 4.00E3a.

d. If there is documented evidence of silent ischemia or restricted activity to prevent chest discomfort, this information must be considered along with all available evidence to determine if an equivalence decision is appropriate.

e. Chest discomfort of myocardial ischemic origin is usually caused by coronary artery disease. However, ischemic discomfort may be caused by noncoronary artery conditions, such as critical aortic stenosis, hypertrophic cardiomyopathy, pulmonary hypertension, or anemia. These conditions should be distinguished from coronary artery disease, because the evaluation criteria, management, and prognosis (duration) may differ from that of coronary artery disease.

f. Chest discomfort of nonischemic origin may result from other cardiac conditions such as pericarditis and mitral valve prolapse. Noncardiac conditions may also produce symptoms mimicking that of myocardial ischemia. These conditions include gastrointestinal tract disorders, such as esophageal spasm, esophagitis, hiatal hernia, biliary tract disease, gastritis, peptic ulcer, and pancreatitis, and musculoskeletal syndromes, such as chest wall muscle spasm, chest wall syndrome (especially after coronary bypass surgery), costochondritis, and cervical or dorsal arthritis. Hyperventilation may also mimic ischemic discomfort. Such disorders should be considered before concluding that chest discomfort is of myocardial ischemic origin.

4. Peripheral arterial disease.

The level of impairment is based on the symptomatology, physical findings, Doppler studies before and after a standard exercise test, or angiographic findings.

The requirements for evaluating peripheral arterial disease in 4.12B are based on the ratio of the systolic blood pressure at the ankle to the systolic blood pressure at the brachial artery, determined in the supine position at the same time. Techniques for obtaining ankle systolic blood pressures include Doppler, plethysmographic studies, or other techniques.

Listing 4.12B1 is met when the resting ankle/brachial systolic blood pressure ratio is less than 0.50. Listing 4.12B2 provides additional criteria for evaluating peripheral arterial impairment on the basis of exercise studies when the resting ankle/brachial systolic blood pressure ratio is 0.50 or above. The decision to obtain exercise studies should be based on an evaluation of the existing clinical evidence, but exercise studies are rarely warranted when the resting ankle-over-brachial systolic blood pressure ratio is 0.80 or above. The results of exercise studies should describe the level of exercise, e.g., speed and grade of the treadmill settings, the duration of exercise, symptoms during exercise, the reasons for stopping exercise if the expected level of exercise was not attained, blood pressures at the ankle and other pertinent sites measured after exercise, and the time required to return the systolic blood pressure toward or to the pre-exercise level. When an exercise Doppler study is purchased by the Social Security Administration, the requested exercise must be on a treadmill at 2 mph on a 10 or 12 percent grade for 5 minutes. Exercise studies should not be performed on individuals for whom exercise poses a significant risk.

Application of the criteria in 4.12B may be limited in individuals who have marked calcific (Monckeberg's) sclerosis of the peripheral arteries or marked small vessel disease associated with diabetes mellitus.

4.01 *Category of Impairments, Cardiovascular System*

4.02 *Chronic heart failure* while on a regimen of prescribed treatment (see 4.00A if there is no regimen of prescribed treatment). With one of the following:

A. Documented cardiac enlargement by appropriate imaging techniques (e.g., a cardiothoracic ratio of greater than 0.50 on a PA chest x-ray with good inspiratory effort or left ventricular diastolic diameter of greater than 5.5 cm on two-dimensional echocardiography), resulting in inability to carry on any physical activity, and with symptoms of inadequate cardiac output, pulmonary congestion, systemic congestion, or anginal syndrome at rest (e.g., recurrent or persistent fatigue, dyspnea, orthopnea, anginal discomfort);

Or

B. Documented cardiac enlargement by appropriate imaging techniques (see 4.02A) or ventricular dysfunction manifested by S3, abnormal wall motion, or

left ventricular ejection fraction of 30 percent or less by appropriate imaging techniques; and

1. Inability to perform on an exercise test at a workload equivalent to 5 METs or less due to symptoms of chronic heart failure, or, in rare instances, a need to stop exercise testing at less than this level of work because of:

a. Three or more consecutive ventricular premature beats or three or more multiform beats; or

b. Failure to increase systolic blood pressure by 10 mmHg, or decrease in systolic pressure below the usual resting level (see 4.00C2b); or

c. Signs attributable to inadequate cerebral perfusion, such as ataxic gait or mental confusion, and

2. Resulting in marked limitation of physical activity, as demonstrated by fatigue, palpitation, dyspnea, or anginal discomfort on ordinary physical activity, even though the individual is comfortable at rest;

Or

C. Cor pulmonale fulfilling the criteria in 4.02A or B.

4.03 *Hypertensive cardiovascular disease.* Evaluate under 4.02 or 4.04, or under the criteria for the affected body system (2.02 through 2.04, 6.02, or 11.04A or B).

4.04 *Ischemic heart disease,* with chest discomfort associated with myocardial ischemia, as described in 4.00E3, while on a regimen of prescribed treatment (see 4.00A if there is no regimen of prescribed treatment). With one of the following:

A. Symptom – and sign-limited exercise test demonstrating at least one of the following manifestations at a workload equivalent to 5 METs or less:

1. Horizontal or downsloping depression, in the absence of digitalis glycoside therapy and/or hypokalemia, of the ST segment of at least -0.10 millivolts (-1.0 mm) in at least 3 consecutive complexes that are on a level baseline in any lead (other than aVR) and that have a typical ischemic time course of development and resolution (progression of horizontal or downsloping ST depression with exercise, and persistence of depression of at least -0.10 millivolts for at least 1 minute of recovery); or

2. An upsloping ST junction depression, in the absence of digitalis glycoside therapy and/or hypokalemia, in any lead (except aVR) of at least -0.2 millivolts or more for at least 0.08 seconds after the J junction and persisting for at least 1 minute of recovery; or

3. At least 0.1 millivolt (1 mm) ST elevation above resting baseline during both exercise and 3 or more minutes of recovery in ECG leads with low R and T waves in the leads demonstrating the ST segment displacement; or

4. Failure to increase systolic pressure by 10 mmHg, or decrease in systolic pressure below usual clinical resting level (see 4.00C2b); or

5. Documented reversible radionuclide "perfusion" (thallium^{201}) defect at an exercise level equivalent to 5 METs or less;

Or

B. Impaired myocardial function, documented by evidence (as outlined under 4.00C3 or 4.00C4b) of hypokinetic, akinetic, or dyskinetic myocardial free wall or septal wall motion with left ventricular ejection fraction of 30 percent or less, and an evaluating program physician, preferably one experienced in the care of patients with cardiovascular disease, has concluded that performance of exercise testing would present a significant risk to the individual, and resulting in marked limitation of physical activity, as demonstrated by fatigue, palpitation, dyspnea, or anginal discomfort on ordinary physical activity, even though the individual is comfortable at rest;

Or

C. Coronary artery disease, demonstrated by angiography (obtained independent of Social Security disability evaluation), and an evaluating program physician, preferably one experienced in the care of patients with cardiovascular disease, has concluded that performance of exercise testing would present a significant risk to the individual, with both 1 and 2:

1. Angiographic evidence revealing:

a. 50 percent or more narrowing of a nonbypassed left main coronary artery; or

b. 70 percent or more narrowing of another nonbypassed coronary artery; or

c. 50 percent or more narrowing involving a long (greater than 1 cm) segment of a nonbypassed coronary artery; or

d. 50 percent or more narrowing of at least 2 nonbypassed coronary arteries; or

e. Total obstruction of a bypass graft vessel; and

2. Resulting in marked limitation of physical activity, as demonstrated by fatigue, palpitation, dyspnea, or anginal discomfort on ordinary physical activity, even though the individual is comfortable at rest.

4.05 *Recurrent arrhythmias,* not related to reversible causes such as electrolyte abnormalities or digitalis glycoside or antiarrhythmic drug toxicity, resulting in uncontrolled repeated episodes of cardiac syncope or near syncope and arrhythmia despite prescribed treatment (see 4.00A if there is no prescribed treatment), documented by resting or ambulatory (Holter) electrocardiography coincident with the occurrence of syncope or near syncope.

4.06 *Symptomatic congenital heart disease* (cyanotic or acyanotic), documented by appropriate imaging techniques (as outlined under 4.00C3) or cardiac catheterization. With one of the following:

A. Cyanosis at rest, and:

1. Hematocrit of 55 percent or greater, or

2. Arterial O_2 saturation of less than 90 percent in room air, or resting arterial PO_2 of 60 Torr or less:

Or

B. Intermittent right-to-left shunting resulting in cyanosis on exertion (e.g., Eisenmenger's physiology) and with arterial PO_2 of 60 Torr or less at a workload equivalent to 5 METs or less;

Or

C. Chronic heart failure with evidence of ventricular dysfunction, as described in 4.02;

Or

D. Recurrent arrhythmias as described in 4.05;

Or

E. Secondary pulmonary vascular obstructive disease with a mean pulmonary arterial pressure elevated to at least 70 percent of the mean systemic arterial pressure.

4.07 *Valvular heart disease or other stenotic defects, or valvular regurgitation,* documented by appropriate imaging techniques or cardiac catheterization. Evaluate under the criteria in 4.02, 4.04, 4.05, or 11.04.

4.08 *Cardiomyopathies,* documented by appropriate imaging techniques or cardiac catheterization. Evaluate under the criteria in 4.02, 4.04, 4.05, or 11.04.

4.09 *Cardiac transplantation.* Consider under a disability for 1 year following surgery; thereafter, reevaluate residual impairment under 4.02 to 4.08.

4.10 *Aneurysm of aorta or major branches,* due to any cause (e.g., atherosclerosis, cystic medial necrosis, Marfan syndrome, trauma), demonstrated by an appropriate imaging technique. With one of the following:

A. Acute or chronic dissection not controlled by prescribed medical or surgical treatment;

Or

B. Chronic heart failure as described under 4.02;

Or

C. Renal failure as described under 6.02;

Or

D. Neurological complications as described under 11.04.

4.11 *Chronic venous insufficiency* of a lower extremity. With incompetency or obstruction of the deep venous system and one of the following;

A. Extensive brawny edema;

Or

B. Superficial varicosities, stasis dermatitis, and recurrent or persistent ulceration which has not healed following at least 3 months of prescribed medical or surgical therapy.

4.12 *Peripheral arterial disease.* With one of the following:

A. Intermittent claudication with failure to visualize (on arteriogram obtained independent of Social Security disability evaluation) the common femoral or deep femoral artery in one extremity;

Or

B. Intermittent claudication with marked impairment of the peripheral arterial circulation as determined by Doppler studies showing:

1. Resting ankle/brachial systolic blood pressure ratio of less than 0.50; or

2. Decrease in systolic blood pressure at the ankle on exercise (see 4.00E4) of 50 percent or more of pre-exercise level at the ankle, and requiring 10 minutes or more to return to pre-exercise level;

Or

C. Amputation at or above the tarsal region due to peripheral vascular disease.

5.00 Digestive System

A. *Disorders of the Digestive System* which result in a marked impairment usually do so because of interference with nutrition, multiple recurrent inflammatory lesions, or complications of disease, such as fistulae, abscesses, or recurrent obstruction. Such complications usually respond to treatment. These

complications must be shown to persist on repeated examinations despite therapy for a reasonable presumption to be made that a marked impairment will last for a continuous period of at least 12 months.

B. *Malnutrition or Weight Loss* from gastrointestinal disorders. When the primary disorder of the digestive tract has been established (e.g., enterocolitis, chronic pancreatitis, postgastrointestinal resection, or esophageal stricture, stenosis, or obstruction) the resultant interference with nutrition will be considered under the criteria in 5.08. This will apply whether the weight loss is due to primary or secondary disorders of malabsorption, malassimilation or obstruction. However, weight loss not due to diseases of the digestive tract, but associated with psychiatric or primary endocrine or other disorders, should be evaluated under the appropriate criteria for the underlying disorder.

C. *Surgical Diversion of the Intestinal Tract,* including colostomy or ileostomy, are not listed since they do not represent impairments which preclude all work activity if the individual is able to maintain adequate nutrition and function of the stoma. Dumping syndrome which may follow gastric resection rarely represents a marked impairment which would continue for 12 months. Peptic ulcer disease with recurrent ulceration after definitive surgery ordinarily responds to treatment. A recurrent ulcer after definitive surgery must be demonstrated on repeated upper gastrointestinal roentgenograms or gastroscopic examinations despite therapy to be considered a severe impairment which will last for at least 12 months. Definitive surgical procedures are those designed to control the ulcer disease process (i.e, vagotomy and pyloroplasty, subtotal gastrectomy, etc.). Simple closure of a perforated ulcer does not constitute definitive surgical therapy for peptic ulcer disease.

5.01 Category of Impairments, Digestive System

5.02 *Recurrent Upper Gastrointestinal Hemorrhage from undetermined cause* with anemia manifested by hematocrit of 30 percent or less on repeated examinations.

5.03 *Stricture, Stenosis, or Obstruction of the Esophagus (demonstrated by X-ray or endoscopy)* with weight loss as described under 5.08.

5.04 *Peptic Ulcer Disease (demonstrated by X-ray or endoscopy.* With:

A. Recurrent ulceration after definitive surgery persistent despite therapy; or

B. *I*noperable fistula formation; or

C. Recurrent Obstruction demonstrated by X-ray or endoscopy. or

D. Weight loss as described under 5.08.

5.05 *Chronic Liver Disease (e.g., portal, postnecrotic, or biliary cirrhosis; chronic active hepatitis; Wilson's disease).* With:

A. Esophageal Varices (demonstrated by X-ray or endoscopy) with a documented history of massive hemorrhage attributable to these varices.

Consider under disability for 3 years following the last massive hemorrhage; thereafter, evaluate the residual impairment; or

B. Performance of a shunt operation for esophageal varices. Consider under a disability for 3 years following surgery; thereafter, evaluate the residual impairment; or

C. Serum bilirubin of 2.5 mg. per deciliter (100 ml.) or greater persisting on repeated examinations for at least 5 months; or

D. Ascites, not attributable to other causes, recurrent or persisting for at least 5 months, demonstrated by abdominal paracentesis or associated with persistent hypoalbuminemia of 3.0 gm. per deciliter (100 ml.) or less; or

E. Hepatic encephalopathy. Evaluate under the criteria in 12.02; or

F. Confirmation of chronic liver disease by liver biopsy (obtained independent of Social Security disability evaluation) and one of the following:

1. Ascites not attributable to other causes, recurrent or persisting for at least 3 months, demonstrated by abdominal paracentesis or associated with persistent hypoalbuminemia of 3.0 gm. per deciliter (100 ml.) or less; or

2. Serum bilirubin of 2.5 mg. per deciliter (100 ml.) or greater on repeated examinations for at least 3 months; or

3. Hepatic cell necrosis or inflammation, persisting for at least 3 months, documented by repeated abnormalities of prothrombin time and enzymes indicative of hepatic dysfunction.

5.06 *Chronic Ulcerative or Granulomatous Colitis (demonstrated by endoscopy, barium enema, biopsy, or operative findings).* With:

A. Recurrent Bloody Stools documented on repeated examinations and anemia manifested by hematocrit of 30 percent or less on repeated examinations; or

B. Persistent or recurrent systemic manifestations. such as arthritis, iritis, fever, or liver dysfunction, not attributable to other causes; or

C. Intermittent obstruction due to intractable abscess, fistula formation, or stenosis; or

D. Recurrence of findings of A, B, or C, above after total colectomy: or

E. Weight loss as described under 5.08

5.07 Regional Enteritis (Demonstrated by operative findings, barium studies, biopsy, or endoscopy). With:

A. Persistent or recurrent intestinal obstruction evidenced by abdominal pain, distention, nausea, and vomiting and accompanied by stenotic areas of small bowel with proximal intestinal dilation; or

B. Persistent or recurrent systemic manifestations such as arthritis, iritis, fever, or liver dysfunction, not attributable to other causes; or

C. Intermittent obstruction due to intractable abscess or fistula formation; or

D. Weight loss as described under 5.08.

5.08 *Weight Loss due to any persisting gastrointestinal disorder:* (The following weights are to be demonstrated to have persisted for at least 3 months despite prescribed therapy and expected to persist at this level for at least 12 months.) With:

A. *Weight equal to or less than the values specified in Table I or II;* or

B. *Weight equal to or less than the values specified in Table III or IV and one of the following abnormal findings on repeated examinations:*

1. Serum albumin of 3.0 gm. per deciliter (100 ml.) or less; or

2. Hematocrit of 30 percent or less; or

3. Serum calcium of 8.0 mg. per deciliter (100 ml.) (4.0 mEq./L) or less; or

4. Uncontrolled diabetes mellitus due to pancreatic dysfunction with repeated hyperglycemia, hypoglycemia, or ketosis; or

5. Fat in stool of 7 gm. or greater per 24-hour stool specimen; or

6. Nitrogen in stool of 3 gm. or greater per 24-hour specimen; or

7. Persistent or recurrent ascites or edema not attributable to other causes.

Tables of Weight Reflecting Malnutrition Scaled According to Height and Sex– To be used only in connection with 5.08.

Table I – Men

Height without shoes (inches)	Weight (pounds)
61	90
62	92
63	94
64	97
65	99
66	102
67	106
68	109
69	112
70	115
71	118
72	122
73	125
74	128
75	131
76	134

Table II – Women

Height without shoes (inches)	Weight (pounds)
58	77
59	79
60	82
61	84
62	86
63	89
64	91
65	94
66	98
67	101
68	104
69	107
70	110
71	114
72	117
73	120

Table III – Men

Height without shoes (inches)	Weight (pounds)
61	95
62	98
63	100
64	103
65	106
66	109
67	112
68	116
69	119
70	122
71	126
72	129
73	133
74	136
75	139
76	143

Table IV – Women

Height without shoes (inches)	Weight (pounds)
58	82
59	84
60	87
61	89
62	92
63	94
64	97
65	100
66	104
67	107
68	111
69	114
70	117
71	121
72	124
73	128

6.00 Genito-Urinary System

A. *Determination of the presence of chronic renal disease* will be based upon (1) a history, physical examination, and laboratory evidence of renal disease, and (2) indications of its progressive nature or laboratory evidence of deterioration of renal function.

B. *Nephrotic Syndrome*. The medical evidence establishing the clinical diagnosis must include the description of extent of tissue edema, including pretibial, periorbital, or presacral edema. The presence of ascites, pleural effusion, pericardial effusion, and hydroarthrosis should be described if present. Results of pertinent laboratory tests must be provided. If a renal biopsy has been performed, the evidence should include a copy of the report of microscopic examination of the specimen. Complications such as severe orthostatic hypotension, recurrent infections or venous thromboses should be evaluated on the basis of resultant impairment.

C. *Hemodialysis, peritoneal dialysis, and kidney transplantation.* When an individual is undergoing periodic dialysis because of chronic renal disease, severity of impairment is reflected by the renal function prior to the institution of dialysis.

The amount of function restored and the time required to effect improvement in an individual treated by renal transplant depend upon various factors, including adequacy of post transplant renal function, incidence and severity of renal infection, occurrence of rejection crisis, the presence of systemic complications (anemia, neuropathy, etc.), and side effects of corticosteroids or immuno-suppressive agents. A convalescent period of at least 12 months is required before it can be reasonably determined whether the individual has reached a point of stable medical improvement.

D. *Evaluate associated disorders and complications* according to the appropriate body system Listing.

6.01 Category of Impairments, Genito-Urinary System

6.02 *Impairment of Renal Function,* due to any chronic renal disease expected to last 12 months (e.g., hypertensive vascular disease, chronic nephritis, nephrolitiasis, polycystic disease, bilateral hydronephrosis, etc) With:

A. *Chronic hemodialysis or peritoneal dialysis* necessitated by irreversible renal failure: or

B. *Kidney transplant.* Consider under a disability for 12 months following surgery; thereafter, evaluate the residual impairment (see 6.00C); or

C. *Persistent elevation of serum creatinine* to 4 mg. per deciliter (100 ml.) or greater or reduction of creatinine clearance to 20 ml. per minute (29 liters/ 24 hours) or less, over at least 3 months, with one of the following:

1. *Renal osteodystrophy* manifested by severe bone pain and appropriate radiographic abnormalities (e.g., osteitis fibrosa, marked osteoporosis, pathologic fractures); or

2. *A clinical episode of pericarditis;* or

3. *Persistent motor or sensory neuropathy*; or

4. *Intractable pruritus*; or

5. Persistent fluid overload syndrome resulting in diastolic hypertension (110 mm. or above) or signs of vascular congestion; or

6. *Persistent anorexia* with recent weight loss and current weight meeting the values in 5.08, Table III or IV; or

7. *Persistent hematocrits* of 30 percent or less.

6.06 *Nephrotic syndrome, with significant anasarca, persistent for at least 3 months despite prescribed therapy.* With:

A. *Serum albumin* of 3.0 gm. per deciliter (100 ml.) or less and proteinuria of 3.5 gm. per 24 hours or greater; or

B. *Proteinuria* of 10.0 gm. per 24 hours or greater.

7.00 Hemic and Lymphatic System

A. *Impairment caused by anemia* should be evaluated according to the ability of the individual to adjust to the reduced oxygen-carrying capacity of the blood. A gradual reduction in red cell mass, even to very low values, is often well tolerated in individuals with a healthy cardiovascular system.

B. *Chronicity is indicated* by persistence of the condition for at least 3 months. The laboratory findings cited must reflect the values reported on more than one examination over that 3-month period.

C. *Sickle cell disease* refers to a chronic hemolytic anemia associated with sickle cell hemoglobin, either homozygous or in combination with thalassemia or with another abnormal hemoglobin (such as C or F).

Appropriate hematologic evidence for sickle cell disease, such as hemoglobin electrophoresis, must be included. Vaso-occlusive or aplastic episodes should be documented by description of severity, frequency, and duration.

Major visceral episodes include meningitis, osteomyelitis, pulmonary infections or infarctions, cerebrovascular accidents, congestive heart failure, genito-urinary involvement, etc.

D. *Coagulation defects.* Chronic inherited coagulation disorders must be documented by appropriate laboratory evidence. Prophylactic therapy such as with antihemophilic globulin (AHG) concentrate does not in itself imply severity.

E. *Acute leukemia.* Initial diagnosis of acute leukemia must be based upon definitive bone marrow pathologic evidence. Recurrent disease may be documented by peripheral blood, bone marrow, or cerebrospinal fluid examination. The pathology report must be included.

The acute phase of chronic myelocytic (granulocytic) leukemia should be considered under the requirements for acute leukemia.

The criteria in 7.11 contain the designated duration of disability implicit in the finding of a listed impairment. Following the designated time period, a documented diagnosis itself is no longer sufficient to establish a marked impairment. The level of any remaining impairment must be evaluated on the basis of the medical evidence.

7.01 Category of Impairments, Hemic and Lymphatic System

7.02 *Chronic anemia (hematocrit persisting at 30 percent or less due to any cause).* With:

A. Requirement of one or more blood transfusions on an average of at least once every 2 months; or

B. Evaluation of the resulting impairment under criteria for the affected body system.

7.05 *Sickle cell disease, or one of its variants.* With:

A. Documented painful (thrombotic) crises occurring at least three times during the 5 months prior to adjudication; or

B. Requiring extended hospitalization (beyond emergency care) at least three times during the 12 months prior to adjudication; or

C. Chronic, severe anemia with persistence of hematocrit of 26 percent or less; or

D. Evaluate the resulting impairment under the criteria for the affected body system.

7.06 *Chronic thrombocytopenia (due to any cause),* with platelet counts repeatedly below 40,000/ cubic millimeter. With:

A. At least one spontaneous hemorrhage, requiring transfusion, within 5 months prior to adjudication; or

B. Intracranial bleeding within 12 months prior to adjudication.

7.07 *Hereditary telangiectasia* with hemorrhage requiring transfusion at least three times during the 5 months prior to adjudication.

7.08 Coagulation defects (hemophilia or a similar disorder) with spontaneous hemorrhage requiring transfusion at least three times during the 5 months prior to adjudication.

7.09 *Polycythemia vera (with erythrocytosis, splenomegaly, and leukocytosis or thrombocytosis).* Evaluate the resulting impairment under the criteria for the affected body system.

7.10 *Myelofibrosis (myeloproliferative syndrome).* With:

A. Chronic anemia. Evaluate according to the criteria of 7.02; or

B. Documented recurrent systemic bacterial infections occurring at least 3 times during the 5 months prior to adjudication; or

C. Intractable bone pain with radiologic evidence of osteosclerosis.

7.11 *Acute leukemia.* Consider under a disability for 2 1/2 years from the time of initial diagnosis.

7.12 *Chronic leukemia.* Evaluate according to the criteria of 7.02, 7.06, 7.10B, 7.11, 7.17, or 13.06A.

7.13 *Lymphomas.* Evaluate under the criteria in 13.06A.

7.14 *Macroglobulinemia or heavy chain disease,* confirmed by serum or urine protein electrophoresis or immunoelectrophoresias. Evaluate impairment under criteria for affected body system or under 7.02, 7.06, or 7.08.

7.15 *Chronic granulocytopenia (due to any cause).* With both A and B below:

A. Absolute neutrophil counts repeatedly below 1,000 cells/cubic millimeter; and

B. Documented recurrent systemic bacterial infections occurring at least 3 times during the 5 months prior to adjudication.

7.16 *Myeloma (confirmed by appropriate serum or urine protein electrophoresis and bone marrow findings).* With:

A. Radiologic evidence of bony involvement with intractable bone pain; or

B. Evidence of renal impairment as described in 6.02; or

C. Hypercalcemia with serum calcium levels persistently greater than 11 mg. per deciliter (100 ml.) for at least 1 month despite prescribed therapy; or

D. Plasma cells (100 or more cells/ cubic millimeter) in the peripheral blood.

7.17 *Aplastic anemias or hematologic malignancies (excluding acute leukemia):* With bone marrow transplantation. Consider under a disability for 12 months following transplantation; thereafter, evaluate according to the primary characteristics of the residual impairment.

8.00 Skin

A. *Skin lesions may result in a marked, long-lasting impairment* if they involve extensive body areas or critical areas such as the hands or feet and become resistant to treatment. These lesions must be shown to have persisted for a sufficient period of time despite therapy for a reasonable presumption to be made that a marked impairment will last for a continuous period of at least 12 months. The treatment for some of the skin diseases listed in this section may require the use of high dosage of drugs with possible serious side effects; these side effects should be considered in the overall evaluation of impairment.

B. *When skin lesions are associated with systemic disease* and where that is the predominant problem, evaluation should occur according to the criteria in the appropriate section. Disseminated (systemic) lupus erythematosus and scleroderma usually involve more than one body system and should be evaluated under 14.02 and 14.04. Neoplastic skin lesions should be evaluated under 13.00ff. When skin lesions (including burns) are associated with contractures or limitation of joint motion, that impairment should be evaluated under 1.00ff.

8.01 Category of Impairments, Skin

8.02 *Exfoliative dermatitis, ichthyosis, ichthyosiform erythroderma.* With extensive lesions not responding to prescribed treatment.

8.03 *Pemphigus, erythema multiforme bullosum, bullous pemphigoid, dermatitis herpetiformis.* With extensive lesions not responding to prescribed treatment.

8.04 *Deep mycotic infections. With extensive fungating, ulcerating lesions not responding to prescribed treatment.*

8.05 *Psoriasis, atopic dermatitis, dyshidrosis.* With extensive lesions, including involvement of the hands or feet which impose a marked

limitation of function and which are not responding to prescribed treatment.

8.06 *Hydradenitis suppurative, acne conglobata.* With extensive lesions involving the axillae or perineum not responding to prescribed medical treatment and not amenable to surgical treatment.

9.00 Endocrine System and Obesity

Cause of impairment. Impairment is caused by overproduction or underproduction of hormones, resulting in structural or functional changes in the body. Where involvement of other organ systems has occurred as a result of a primary endocrine disorder, these impairments should be evaluated according to the criteria under the appropriate sections.

Long-term massive obesity will usually be associated with disorders of the musculoskeletal, cardiovascular, peripheral vascular, and pulmonary systems, and the occurrence of these disorders is the major cause of disability at the listing level. Extreme obesity results in restrictions imposed by body weight and the additional restrictions imposed by disturbances in other body systems.

The weight-bearing criterion in 9.09A refers to the lumbosacral spine. The cervical and thoracic spines are not considered weight-bearing.

9.01 Category of Impairments, Endocrine System and Obesity

9.02 *Thyroid Disorders.* With:

A. *Progressive exophthalmos* as measured by exophthalmometry; or

B. Evaluate the resulting impairment under the criteria for the affected body system.

9.03 *Hyperparathyroidism.* With:

A. *Generalized decalcification of bone* on X-ray study and elevation of plasma calcium to 11 mg. per deciliter (100 ml) or greater; or

B. A resulting impairment. Evaluate according to the criteria in the affected body system.

9.04 *Hypoparathyroidism.* With:

A. *Severe recurrent tetany;* or

B. *Recurrent generalized convulsions;* or

C. *Lenticular cataracts.* Evaluate under the criteria in 2.00ff.

9.05 *Neurohypophyseal insufficiency (diabetes insipidus).* With urine specific gravity of 1.005 or below, persistent for at least 3 months and recurrent dehydration.

9.06 *Hyperfunction of the adrenal cortex.* Evaluate the resulting impairment under the criteria for the affected body system.

9.08 *Diabetes mellitus.* With:

A. *Neuropathy* demonstrated by significant and persistent disorganization of motor function in two extremities resulting in sustained disturbance of gross and dexterous movements, or gait and station (see 11.00C), or

B. *Acidosis* occurring at least on the average of once every 2 months documented by appropriate blood chemical tests (pH or pCO2 or bicarbonate levels); or

C. *Amputation at, or above, the tarsal region* due to diabetic necrosis or peripheral arterial disease; or

D. *Retinitis proliferans;* evaluate the visual impairment under the criteria in 2.02, 2.03, or 2.04.

9.09 *Obesity.* Weight equal to or greater than the values specified in Table I for males, Table II for females (100 percent above desired level), and one of the following:

A. History of pain and limitation of motion in any weight-bearing joint or the lumbosacral spine (on physical examination) associated with findings on medically acceptable imaging techniques of arthritis in the affected joint or lumbosacral spine; or

B. Hypertension with diastolic blood pressure persistently in excess of 100 mm. Hg measured with appropriate size cuff; or

C. History of congestive heart failure manifested by past evidence of vascular congestion such as hepatomegaly, peripheral or pulmonary edema; or

D. Chronic venous insufficiency with superficial varicosities in a lower extremity with pain on weight bearing and persistent edema; or

E. Respiratory disease with total forced vital capacity equal to or less than 2.0 L. or a level of hypoxemia at rest equal to or less than the values specified in Table-III A or III-B or III-C.

Table I – Men
[metric]

Height without shoes (centimeters)	Weight (kilograms)
152	112
155	115
157	117
160	120
163	123
165	125
168	129
170	134
173	137
175	141
178	145
180	149
183	153
185	157
188	162
190	165
193	170

Table II – Women
~ [metric]

Height without shoes (centimeters)	Weight (kilograms)
142	95
145	96
147	99
150	102
152	105
155	107
157	110
160	114
163	117
165	121
168	125
170	128
173	132
175	135
178	139
180	143
183	146

Table I – Men

Height without shoes (inches)	Weight (pounds)
60	246
61	252
62	258
63	264
64	270
65	276
66	284
67	294
68	302
69	310
70	318
71	328
72	336
73	346
74	356
75	364
76	374

Table II – Women

Height without shoes (inches)	Weight (pounds)
56	208
57	212
58	218
59	224
60	230
61	236
62	242
63	250
64	258
65	266
66	274
67	282
68	290
69	298
70	306
71	314
72	322

Table III – A
(Applicable at test sites less than 3,000 feet above sea level)

Arterial PCO2 (mm. Hg) and	Arterial PO2 Equal to or Less than (mm. Hg)
30 or below	65
31	64
32	63T
33	62
34	T61
35	60
36	59
37	58
38	57
39	56
40 or above	55

Table III – B
(Applicable at test sites 3,000 through 6,000 feet above sea level)

Arterial PCO2 (mm. Hg) and	Arterial PO2 Equal to or Less than (mm. Hg)
30 or below	60
31	59
32	58
33	57
34	56
35	55
36	54
37	53
38	52
39	51
40 or above	50

Table III – C
(Applicable at test sites over 6,000 feet above sea level)

Arterial PCO2 (mm. Hg) and	Arterial PO2 Equal to or Less than (mm. Hg)
30 or below	55
31	54
32	53
33	52
34	51
35	50
36	49
37	48
38	47
39	46
40 or above	45

11.00 Neurological

A. C*onvulsive disorders.* In convulsive disorders, regardless of etiology, degree of impairment will be determined according to type, frequency, duration, and sequelae of seizures. At least one detailed description of a typical seizure is required. Such description includes the presence or absence of aura, tongue bites, sphincter control, injuries associated with the attack, and postictal

phenomena. The reporting physician should indicate the extent to which description of seizures reflects his own observations and the source of ancillary information. Testimony of persons other than the claimant is essential for description of type and frequency of seizures if professional observation is not available.

Documentation of epilepsy should include at least one electroencephalogram (EEG).

Under 11.02 and 11.03, the criteria can be applied only if the impairment persists despite the fact that the individual is following prescribed anticonvulsive treatment. Adherence to prescribed anticonvulsant therapy can ordinarily be determined from objective clinical findings in the report of the physician currently providing treatment for epilepsy. Determination of blood levels of phenytoin sodium or other anticonvulsive drugs may serve to indicate whether the prescribed medication is being taken. When seizures are occurring at the frequency stated in 11.02 or 11.03, evaluation of the severity of the impairment must include consideration of the serum drug levels. Should serum drug levels appear therapeutically inadequate, consideration should be given as to whether this is caused by individual idiosyncrasy in absorption or metabolism of the drug. Blood drug levels should be evaluated in conjunction with all other evidence to determine the extent of compliance. When the reported blood drug levels are low, therefore, the information obtained from the treating source should include the physician's statement as to why the levels are low and the results of any relevant diagnostic studies concerning the blood levels. Where adequate seizure control is obtained only with unusually large doses, the possibility of impairment resulting from the side effects of this medication must also be assessed. Where documentation shows that use of alcohol or drugs affects adherence to prescribed therapy or may play a part in the precipitation of seizures, this must also be considered in the overall assessment of impairment level.

B. *Brain tumors.* The diagnosis of malignant brain tumors must be established, and the persistence of the tumor should be evaluated, under the criteria described in 13.00 B and C for neoplastic disease.

In histologically malignant tumors, the pathological diagnosis alone will be the decisive criterion for severity and expected duration (see 11.05A). For other tumors of the brain, the severity and duration of the impairment will be determined on the basis of symptoms, signs, and pertinent laboratory findings (11.05B).

C. *Persistent disorganization of motor function* in the form of paresis or paralysis, tremor or other involuntary movements, ataxia and sensory disturbances (any or all of which may be due to cerebral, cerebellar, brain stem, spinal cord, or peripheral nerve dysfunction) which occur singly or in various combinations, frequently provides the sole or partial basis for decision in cases of neurological impairment. The assessment of impairment depends on the degree of interference with locomotion and/or interference with the use of fingers, hands and arms.

D. *In conditions which are episodic in character,* such as multiple sclerosis or myasthenia gravis, consideration should be given to frequency and duration of exacerbations, length of remissions, and permanent residuals.

E *Multiple sclerosis.* The major criteria for evaluating impairment caused by multiple sclerosis are discussed in listing 11.09. Paragraph A provides criteria for evaluating disorganization of motor function and gives reference to 11.04B (11.04B then refers to 11.00C). Paragraph B provides references to other listings for evaluating visual or mental impairments caused by multiple sclerosis. Paragraph C provides criteria for evaluating the impairment of individuals who do not have muscle weakness or other significant disorganization of motor function at rest, but who do develop muscle weakness on activity as a result of fatigue.

Use of the criteria in 11.09C is dependent upon (1) documenting a diagnosis of multiple sclerosis, (2) obtaining a description of fatigue considered to be characteristic of multiple sclerosis, and (3) obtaining evidence that the system has actually become fatigued. The evaluation of the magnitude of the impairment must consider the degree of exercise and the severity of the resulting muscle weakness.

The criteria in 11.09C deal with motor abnormalities which occur on activity. If the disorganization of motor function is present at rest, paragraph A must be used, taking into account any further increase in muscle weakness resulting from activity.

Sensory abnormalities may occur, particularly involving central visual acuity. The decrease in visual acuity may occur after brief attempts at activity involving near vision, such as reading. This decrease in visual acuity may not persist when the specific activity is terminated, as with rest, but is predictably reproduced with resumption of the activity. The impairment of central visual acuity in these cases should be evaluated under the criteria in Listing 2.02, taking into account the fact that the decrease in visual acuity will wax and wane.

Clarification of the evidence regarding central nervous system dysfunction responsible for the symptoms may require supporting technical evidence of functional impairment such as evoked response tests during exercise.

11.01 Category Of Impairments, Neurological

11.02 *Epilepsy – major motor seizures, (grand mal or psychomotor), documented by EEG and by detailed description of a typical seizure pattern, including all associated phenomena; occurring more frequently than once a month, in spite of at least 3 months of prescribed treatment. With*:

A. Daytime episodes (loss of consciousness and convulsive seizures) or

B. Nocturnal episodes manifesting residuals which interfere significantly with activity during the day.

11.03 *Epilepsy - Minor motor seizures (petit mal, psychomotor, or focal), documented by EEG and by detailed description of a typical seizure pattern including all associated phenomena; occurring more frequently than once weekly in spite of at least 3 months of prescribed treatment.* With alteration of awareness or loss of consciousness and transient postictal manifestations of unconventional behavior or significant interference with activity during the day.

11.04 *Central nervous system vascular accident.* With one of the following more than 3 months post-vascular accident:

A. Sensory or motor aphasia resulting in ineffective speech or communication; or

B. Significant and persistent disorganization of motor function in two extremities, resulting in sustained disturbance of gross and dexterous movements, or gait and station (see 11.00C).

11.05 *Brain tumors*

A. Malignant gliomas (astrocytoma - grades III and IV, glioblastoma multiforme), medulloblastoma, ependymoblastoma, or primary sarcoma; or

B. Astrocytoma (grades I and II), meningioma, pituitary tumors, oligodendroglioma, ependymoma, clivus chordoma, and benign tumors. Evaluate under 11.02, 11.03, 11.04A or B, or 12.02.

11.06 *Parkinsonian syndrome* with the following signs: Significant rigidity, bradykinesia, or tremor in two extremities, which, singly or in combination, result in sustained disturbance of gross and dexterous movements, or gait and station.

11.07 Cerebral palsy. With:

A. IQ of 70 or less; or

B. Abnormal behavior patterns, such as destructiveness or emotional instability; or

C. Significant interference in communication due to speech, hearing, or visual defect; or

D. Disorganization of motor function as described in 11.04B.

11.08 *Spinal cord or nerve root lesions, due to any cause* with disorganization of motor function as described in 11.04B.

11.09 Multiple sclerosis. With:

A. Disorganization of motor function as described in 11.04B; or

B. Visual or mental impairment as described under the criteria in 2.02, 2.03, 2.04, or 12.02; or

C. Significant, reproducible fatigue of motor function with substantial muscle weakness on repetitive activity, demonstrated on physical examination, resulting from neurological dysfunction in areas of the central nervous system known to be pathologically involved by the multiple sclerosis process.

11.10 Amyo*trophic lateral sclerosis.* With:

A. Significant bulbar signs; or

B. Disorganization of motor function as described in 11.04B.

11.11 *Anterior poliomyelitis.* With:

A. Persistent difficulty with swallowing or breathing; or

B. Unintelligible speech; or

C. Disorganization of motor function as described in 11.04B.

11.12 *Myasthenia gravis.* With:

A. Significant difficulty with speaking, swallowing, or breathing while on prescribed therapy; or

B. Significant motor weakness of muscles of extremities on repetitive activity against resistance while on prescribed therapy.

11.13 *Muscular dystrophy* with disorganization of motor function as described in 11.04B.

11.14 Peripheral neuropathies. With disorganization of motor function as described in 11.04B, in spite of prescribed treatment.

11.15 *Tabes dorsalis.* With:

A. Tabetic crises occurring more frequently than once monthly; or

B. Unsteady, broad-based or ataxic gait causing significant restriction of mobility substantiated by appropriate posterior column signs.

11.16 *Subacute combined cord degeneration (pernicious anemia) with disorganization of motor function as described in 11.04B or 11.15B, not significantly improved by prescribed treatment.*

11.17 *Degenerative disease not listed elsewhere, such as Huntington's chorea, Friedreich's ataxia, and spino-cerebellar degeneration.* With:

A. Disorganization of motor function as described in 11.04B or 11.15B; or

B. Chronic brain syndrome. Evaluate under 12.02.

11.18 *Cerebral trauma:*

Evaluate under the provisions of 11.02, 11.03, 11.04, and 12.02, as applicable.

11.19 Syringomyelia. With:

A. Significant bulbar signs; or

B. Disorganization of motor function as described in 11.04B.

12.00 Mental Disorders

A. *Introduction:* The evaluation of disability on the basis of mental disorders requires the documentation of a medically determinable impairment(s) as well as consideration of the degree of limitation such impairment(s) may impose on the individual's ability to work and whether these limitations have lasted or are expected to last for a continuous period of at least 12 months. The listings for mental disorders are arranged in eight diagnostic categories: organic mental disorders (12.02); schizophrenic, paranoid and other psychotic disorders (12.03); affective disorders (12.04); mental retardation and autism (12.05); anxiety related disorders (12.06); somatoform disorders (12.07); personality disorders (12.08); and substance addiction disorders (12.09). Each diagnostic group except listings 12.05 and 12.09, consists of a set of clinical findings (paragraph A criteria), one or more of which must be met, and which, if met, lead to a test of functional restrictions (paragraph B criteria), two or three of which must also be met. There are additional considerations (paragraph C criteria) in listings 12.03 and 12.06, discussed therein.

The purpose of including the criteria in paragraph A of the listings for mental disorders is to medically substantiate the presence of a mental disorder. Specific signs and symptoms under any of the listings 12.02 through 12.09 cannot be considered in isolation from the description of the mental disorder contained at the beginning of each listing category. Impairments should be analyzed or reviewed under the mental category(ies) which is supported by the individual's clinical findings.

The purpose of including the criteria in paragraphs B and C of the listings for mental disorders is to describe those functional limitations associated with mental disorders which are incompatible with the ability to work. The restrictions listed in paragraphs B and C must be the result of the mental disorder which is manifested by the clinical findings outlined in paragraph A. The criteria included in paragraphs B and C of the listings for mental disorders have been chosen because they represent functional areas deemed essential to work. An individual who is severely limited in these areas as the result of an impairment identified in paragraph A is presumed to be unable to work.

The structure of the listing for substance addiction disorders, listing 12.09, is different from that for the other mental disorder listings. Listing 12.09 is structured as a reference listing; that is, it will only serve to indicate which of the other listed mental or physical impairments must be used to evaluate the behavioral or physical changes resulting from regular use of addictive substances.

The listings for mental disorders are so constructed that an individual meeting or equaling the criteria could not reasonably be expected to engage in gainful work activity.

Individuals who have an impairment with a level of severity which does not meet the criteria of the listings for mental disorders may or may not have the residual functional capacity (RFC) which would enable them to engage in substantial gainful work activity. The determination of mental RFC is crucial to the evaluation of an individual's capacity to engage in substantial gainful work activity when the criteria of the listings for mental disorders are not met or equaled but the impairment is nevertheless severe.

RFC may be defined as a multidimensional description of the work-related abilities which an individual retains in spite of medical impairments. RFC complements the criteria in paragraphs B and C of the listings for mental disorders by requiring consideration of an expanded list of work-related capacities which may be impaired by mental disorder when the impairment is severe but does not meet or equal a listed mental disorder.

B. *Need for Medical Evidence:* The existence of a medically determinable impairment of the required duration must be established by medical evidence consisting of clinical signs, symptoms and/or laboratory or psychological test findings. These findings may be intermittent or persistent depending on the nature of the disorder. Clinical signs are medically demonstrable phenomena which reflect specific abnormalities of behavior, affect, thought, memory, orientation, or contact with reality. These signs are typically assessed by a psychiatrist or psychologist and/or documented by psychological tests. Symptoms are complaints presented by the individual. Signs and symptoms generally cluster together to constitute recognizable clinical syndromes (mental disorders). Both symptoms and signs which are part of the diagnosed mental disorder must be considered in evaluating severity.

C. *Assessment of Severity:* For mental disorders, severity is assessed in terms of the functional limitations imposed by the impairment. Functional limitations are assessed using the criteria in paragraph B of the listings for mental disorders (descriptions of restrictions of activities of daily living; social functioning; concentration, persistence, or pace; and ability to tolerate increased mental demands associated with competitive work). Where "marked" is used as a standard for measuring the degree of limitation, it means more than moderate, but less than extreme. A marked limitation may arise when several activities or functions are impaired or even when only one is impaired, so long as the degree of limitation is such as to seriously interfere with the ability to function independently, appropriately and effectively. Four areas are considered.

1. *Activities of daily living* include adaptive activities such as cleaning, shopping, cooking, taking public transportation, paying bills, maintaining a residence, caring appropriately for one's grooming and hygiene, using telephones and directories, using a post office, etc. In the context of the individual's overall situation, the quality of these activities is judged by their independence, appropriateness and effectiveness. It is necessary to define the extent to which the individual is capable of initiating and participating in activities independent of supervision or direction.

"Marked" is not the number of activities which are restricted but the overall degree of restriction or combination of restrictions which must be judged. For example, a person who is able to cook and clean might still have marked restrictions of daily activities if the person were too fearful to leave the immediate environment of home and neighborhood, hampering the person's ability to obtain treatment or to travel away from the immediate living environment.

2. *Social functioning* refers to an individual's capacity to interact appropriately and communicate effectively with other individuals. Social functioning includes the ability to get along with others, e.g., family members, friends, neighbors, grocery clerks, landlords, bus drivers, etc. Impaired social functioning may be demonstrated by a history of altercations, evictions, firings, fear of strangers, avoidance of interpersonal relationships, social isolation, etc. Strength in social functioning may be documented by an individual's ability to initiate social contacts with others, communicate clearly with others, interact and actively participate in group activities, etc. Cooperative behaviors, consideration for others, awareness of others' feelings, and social maturity also need to be considered. Social functioning in work situations may involve interactions with the public, responding appropriately to persons in authority, e.g., supervisors, or cooperative behaviors involving coworkers.

"Marked" is not the number of areas in which social functioning is impaired, but the overall degree of interference in a particular area or combination of areas of functioning. For example, a person who is highly antagonistic, uncooperative or hostile but is tolerated by local storekeepers may nevertheless have marked restrictions in social functioning because that behavior is not acceptable in other social contexts.

3. *Concentration, persistence and pace* refer to the ability to sustain focused attention sufficiently long to permit the timely completion of tasks commonly found in work settings. In activities of daily living, concentration may be reflected in terms of ability to complete tasks in everyday household routines. Deficiencies in concentration, persistence and pace are best observed in work and work-like settings. Major impairment in this area can often be assessed through direct psychiatric examination and/or psychological testing, although mental status examination or psychological test data alone should not be used to accurately describe concentration and sustained ability to adequately perform work-like tasks. On mental status examinations, concentration is assessed by tasks requiring short-term memory or through tasks such as having the individual subtract serial sevens from 100. In psychological tests of intelligence or memory, concentration is assessed through tasks requiring short-term memory or through tasks that must be completed within established time limits. In work evaluations, concentration, persistence, and pace are assessed through such tasks as filing index cards, locating telephone numbers, or disassembling and reassembling objects. Strengths and weaknesses in areas of concentration can be discussed in terms of frequency of errors, time it takes to complete the task, and extent to which assistance is required to complete the task.

4. *Deterioration or decompensation in work or work-like settings* refers to repeated failure to adapt to stressful circumstances which cause the individual either to withdraw from that situation or to experience exacerbation of signs and symptoms (i.e., decompensation) with an accompanying difficulty in maintaining activities of daily living, social relationships, and/or maintaining concentration, persistence, or pace (i.e., deterioration which may include deterioration of adaptive behaviors). Stresses common to the work environment include decisions, attendance, schedules, completing tasks, interactions with supervisors, interactions with peers, etc.

D. *Documentation:* The presence of a mental disorder should be documented primarily on the basis of reports from individual providers, such as psychiatrists and psychologists, and facilities such as hospitals and clinics. Adequate descriptions of functional limitations must be obtained from these or other sources which may include programs and facilities where the individual has been observed over a considerable period of time.

Information from both medical and nonmedical sources may be used to obtain detailed descriptions of the individual's activities of daily living; social functioning; concentration, persistence, and pace; or ability to tolerate increased mental demands (stress). This information can be provided by programs such as community mental health centers, day care centers, sheltered workshops, etc. It can also be provided by others, including family members, who have knowledge of the individual's functioning. In some cases descriptions of activities of daily living or social functioning given by individuals or treating sources may be insufficiently detailed and/or may be in conflict with the clinical picture otherwise observed or described in the examinations or reports. It is necessary to resolve any inconsistencies or gaps that may exist in order to obtain a proper understanding of the individual's functional restrictions.

An individual's level of functioning may vary considerably over time. The level of functioning at a specific time may seem relatively adequate or, conversely, rather poor. Proper evaluation of the impairment must take any variations in level of functioning into account in arriving at a determination of impairment severity over time. Thus, it is vital to obtain evidence from relevant sources over a sufficiently long period prior to the date of adjudication in order to establish the individual's impairment severity. This evidence should include treatment notes, hospital discharge summaries, and work evaluation or rehabilitation progress notes if these are available.

Some individuals may have attempted to work or may actually have worked during the period of time pertinent to the determination of disability. This may have been an independent attempt at work, or it may have been in conjunction with a community mental health or other sheltered program which may have been of either short or long duration. Information concerning the individual's behavior during any attempt to work and the circumstances surrounding termination of the work effort are particularly useful in determining the individual's ability or inability to function in a work setting.

The results of well-standardized psychological tests such as the Wechsler Adult Intelligence Scale (WAIS), the Minnesota Multiphasic Personality Inventory (MMPI), the Rorschach, and the Thematic Apperception Test (TAT), may be useful in establishing the existence of a mental disorder. For example, the

WAIS is useful in establishing mental retardation, and the MMPI, Rorschach, and TAT may provide data supporting several other diagnoses. Broad-based neuropsychological assessments using, for example, the Halstead-Reitan or the Luria-Nebraska batteries may be useful in determining brain function deficiencies, particularly in cases involving subtle findings such as may be seen in traumatic brain injury. In addition, the process of taking a standardized test requires concentration, persistence, and pace; performance on such tests may provide useful data. Test results should, therefore, include both the objective data and a narrative description of clinical findings. Narrative reports of intellectual assessment should include a discussion of whether or not obtained IQ scores are considered valid and consistent with the individual's developmental history and degree of functional restriction.

In cases involving impaired intellectual functioning, a standardized intelligence test, e.g., the WAIS, should be administered and interpreted by a psychologist or psychiatrist qualified by training and experience to perform such an evaluation. In special circumstances, nonverbal measures, such as the Raven Progressive Matrices, the Leiter international scale, or the Arthur adaptation of the Leiter may be substituted.

Identical IQ scores obtained from different tests do not always reflect a similar degree of intellectual functioning. In this connection, it must be noted that on the WAIS, for example, IQs of 70 and below are characteristic of approximately the lowest 2 percent of the general population. In instances where other tests are administered, it would be necessary to convert the IQ to the corresponding percentile rank in the general population in order to determine the actual degree of impairment reflected by those IQ scores.

In cases where more than one IQ is customarily derived from the test administered, i.e., where verbal, performance, and full-scale IQs are provided as on the WAIS, the lowest of these is used in conjunction with listing 12.05.

In cases where the nature of the individual's intellectual impairment is such that standard intelligence tests, as described above, are precluded, medical reports specifically describing the level of intellectual, social, and physical function should be obtained. Actual observations by Social Security Administration or State agency personnel, reports from educational institutions and information furnished by public welfare agencies or other reliable objective sources should be considered as additional evidence.

E. *Chronic Mental Impairments:* Particular problems are often involved in evaluating mental impairments in individuals who have long histories of repeated hospitalizations or prolonged outpatient care with supportive therapy and medication. Individuals with chronic psychotic disorders commonly have their lives structured in such a way as to minimize stress and reduce their signs and symptoms. Such individuals may be much more impaired for work than their signs and symptoms would indicate. The results of a single examination may not adequately describe these individuals' sustained ability to function. It is, therefore, vital to review all pertinent information relative to the individual's condition, especially at times of increased stress. It is mandatory to attempt to obtain adequate descriptive information from all sources which have treated the individual either currently or in the time period relevant to the decision.

F. *Effects of Structured Settings:* Particularly in cases involving chronic mental disorders, overt symptomatology may be controlled or attenuated by psychosocial factors such as placement in a hospital, board and care facility, or other environment that provides similar structure. Highly structured and supportive settings may greatly reduce the mental demands placed on an individual. With lowered mental demands, overt signs and symptoms of the underlying mental disorder may be minimized. At the same time, however, the individual's ability to function outside of such a structured and/or supportive setting may not have changed. An evaluation of individuals whose symptomatology is controlled or attenuated by psychosocial factors must consider the ability of the individual to function outside of such highly structured settings. (For these reasons the paragraph C criteria were added to Listings 12.03 and 12.06.)

G. *Effects of Medication:* Attention must be given to the effect of medication on the individual's signs, symptoms and ability to function. While psychotropic medications may control certain primary manifestations of a mental disorder, e.g., hallucinations, such treatment may or may not affect the functional limitations imposed by the mental disorder. In cases where overt symptomatology is attenuated by the psychotropic medications, particular attention must be focused on the functional restrictions which may persist. These functional restrictions are also to be used as the measure of impairment severity. (See the paragraph C criteria in Listings 12.03 and 12.06.)

Neuroleptics, the medicines used in the treatment of some mental illnesses, may cause drowsiness, blunted affect or other side effects involving other body systems. Such side effects must be considered in evaluating overall impairment severity. Where adverse effects of medications contribute to the impairment severity and the impairment does not meet or equal the listings but is nonetheless severe, such adverse effects must be considered in the assessment of the mental residual functional capacity.

H. *Effect of Treatment:* It must be remembered that with adequate treatment some individuals suffering with chronic mental disorders not only have their symptoms and signs ameliorated but also return to a level of function close to that of their premorbid status. Our discussion here in 12.00H has been designed to reflect the fact that present day treatment of a mentally impaired individual may or may not assist in the achievement of an adequate level of adaptation required in the work place. (See the paragraph C criteria in Listings 12.03 and 12.06.)

I. *Technique for Reviewing the Evidence in Mental Disorders Claims to Determine Level of Impairment Severity.* A special technique has been developed to ensure that all evidence needed for the evaluation of impairment severity in claims involving mental impairment is obtained, considered and properly evaluated. This technique, which is used in connection with the sequential evaluation process is explained in § 404.1520a and § 416.920a.

12.01 Category of Impairments - Mental

12.02 *Organic Mental Disorders:* Psychological or behavioral abnormalities associated with a dysfunction of the brain. History and physical examination or laboratory tests demonstrate the presence of a specific organic factor judged to be etiologically related to the abnormal mental state and loss of previously acquired functional abilities.

The required level of severity for these disorders is met when the requirements in both A and B are satisfied.

A. Demonstration of a loss of specific cognitive abilities or affective changes and the medically documented persistence of at least one of the following:

1. Disorientation to time and place; or

2. Memory impairment, either short-term (inability to learn new information), intermediate, or long-term (inability to remember information that was known sometime in the past); or

3. Perceptual or thinking disturbances (e.g., hallucinations, delusions); or

4. Change in personality; or

5. Disturbance in mood; or

6. Emotional lability (e.g., explosive temper outbursts, sudden crying, etc.) and impairment in impulse control; or

7. Loss of measured intellectual ability of at least 15 I.Q. points from premorbid levels or overall impairment index clearly within the severely impaired range on neuropsychological testing, e.g., the Luria-Nebraska, Halstead-Reitan, etc; AND

B. Resulting in at least two of the following:

1. Marked restriction of activities of daily living; or

2. Marked difficulties in maintaining social functioning; or

3. Deficiencies of concentration, persistence or pace resulting in frequent failure to complete tasks in a timely manner (in work settings or elsewhere); or

4. Repeated episodes of deterioration or decompensation in work or work-like settings which cause the individual to withdraw from that situation or to experience exacerbation of signs and symptoms (which may include deterioration of adaptive behaviors).

12.03 *Schizophrenic, Paranoid and Other Psychotic Disorders:* Characterized by the onset of psychotic features with deterioration from a previous level of functioning.

The required level of severity for these disorders is met when the requirements in both A and B are satisfied, or when the requirements in C are satisfied.

A. Medically documented persistence, either continuous or intermittent, of one or more of the following:

1. Delusions or hallucinations; or

2. Catatonic or other grossly disorganized behavior, or

3. Incoherence, loosening of associations, illogical thinking, or poverty of content of speech if associated with one of the following:

a. Blunt affect; or

b. Flat affect; or

c. Inappropriate affect;

Or

4. Emotional withdrawal and/or isolation;

And

B. Resulting in at least two of the following:

1. Marked restriction of activities of daily living; or

2. Marked difficulties in maintaining social functioning; or

3. Deficiencies of concentration, persistence or pace resulting in frequent failure to complete tasks in a timely manner (in work settings or elsewhere); or

4. Repeated episodes of deterioration or decompensation in work or work-like settings which cause the individual to withdraw from that situation or to experience exacerbation of signs and symptoms (which may include deterioration of adaptive behaviors).

Or

C. Medically documented history of one or more episodes of acute symptoms, signs, and functional limitations which at the time met the requirements in A and B of this listing, although these symptoms or signs are currently attenuated by medication or psychosocial support, and one of the following:

1. Repeated episodes of deterioration or decompensation in situations which cause the individual to withdraw from that situation or to experience exacerbation of signs or symptoms (which may include deterioration of adaptive behaviors); or

2. Documented current history of two or more years of inability to function outside of a highly supportive living situation.

12.04 *Affective Disorders:* Characterized by a disturbance of mood, accompanied by a full or partial manic or depressive syndrome. Mood refers to a prolonged emotion that colors the whole psychic life; it generally involves either depression or elation.

The required level of severity for these disorders is met when the requirements in both A and B are satisfied.

A. Medically documented persistence, either continuous or intermittent of one of the following;

1. Depressive syndrome characterized by at least four of the following:

a. Anhedonia or pervasive loss of interest in almost all activities; or

b. Appetite disturbance with change in weight; or

c. Sleep disturbance; or

d. Psychomotor agitation or retardation; or

e. Decreased energy; or

f. Feelings of guilt or worthlessness; or

g. Difficulty concentrating or thinking; or

h. Thoughts of suicide; or

i. Hallucinations, delusions, or paranoid thinking; or

2. Manic syndrome characterized by at least three of the following:

a. Hyperactivity; or

b. Pressure of speech; or

c. Flight of ideas; or

d. Inflated self-esteem; or

e. Decreased need for sleep; or

f. Easy distractibility; or

g. Involvement in activities that have a high probability of painful consequences which are not recognized; or

h. Hallucinations, delusions or paranoid thinking;

Or

3. Bipolar syndrome with a history of episodic periods manifested by the full symptomatic picture of both manic and depressive syndromes (and currently characterized by either or both syndromes);

And

B. Resulting in at least two of the following:

1. Marked restriction of activities of daily living; or

2. Marked difficulties in maintaining social functioning; or

3. Deficiencies of concentration, persistence or pace resulting in frequent failure to complete tasks in a timely manner (in work settings or elsewhere); or

4. Repeated episodes of deterioration or decompensation in work or work-like settings which cause the individual to withdraw from that situation or to experience exacerbation of signs and symptoms (which may include deterioration of adaptive behaviors).

12.05 *Mental Retardation and Autism:* Mental retardation refers to a significantly subaverage general intellectual functioning with deficits in adaptive behavior initially manifested during the developmental period (before age 22). (Note: The scores specified below refer to those obtained on the WAIS, and are used only for reference purposes. Scores obtained on other standardized and individually administered tests are acceptable, but the numerical values obtained must indicate a similar level of intellectual functioning.) Autism is a pervasive developmental disorder characterized by social and significant communication deficits originating in the developmental period.

The required level of severity for this disorder is met when the requirements in A, B, C, or D are satisfied.

A. Mental incapacity evidenced by dependence upon others for personal needs (e.g., toileting, eating, dressing, or bathing) and inability to follow directions, such that the use of standardized measures of intellectual functioning is precluded;

Or

B. A valid verbal, performance, or full scale IQ of 59 or less;

Or

C. A valid, verbal, performance, or full scale IQ of 60 through 70 and a physical or other mental impairment imposing additional and significant work-related limitation of function;

Or

D. A valid verbal, performance, or full scale IQ of 60 through 70, or in the case of autism, gross deficits of social and communicative skills, with either condition resulting in two of the following:

1. Marked restriction of activities of daily living; or

2. Marked difficulties in maintaining social functioning; or

3. Deficiencies of concentration, persistence or pace resulting in frequent failure to complete tasks in a timely manner (in work settings or elsewhere); or

4. Repeated episodes of deterioration or decompensation in work or work-like settings which cause the individual to withdraw from that situation or to experience exacerbation of signs and symptoms (which may include deterioration of adaptive behaviors).

12.06 *Anxiety Related Disorders:* In these disorders anxiety is either the predominant disturbance or it is experienced if the individual attempts to master symptoms; for example, confronting the dreaded object or situation in a phobic disorder or resisting the obsessions or compulsions in obsessive compulsive disorders.

The required level of severity for these disorders is met when the requirements in both A and B are satisfied, or when the requirements in both A and C are satisfied.

A. Medically documented findings of at least one of the following:

1. Generalized persistent anxiety accompanied by three out of four of the following signs or symptoms:

a. Motor tension; or

b. Autonomic hyperactivity; or

c. Apprehensive expectation; or

d. Vigilance and scanning; or

2. A persistent irrational fear of a specific object, activity, or situation which results in a compelling desire to avoid the dreaded object, activity, or situation; or

3. Recurrent severe panic attacks manifested by a sudden unpredictable onset of intense apprehension, fear, terror and sense of impending doom occurring on the average of at least once a week; or

4. Recurrent obsessions or compulsions which are a source of marked distress; or

5. Recurrent and intrusive recollection of a traumatic experience, which are a source of marked distress;

And

B. Resulting in at least two of the following:

1. Marked restriction of activities of daily living; or

2. Marked difficulties in maintaining social functioning; or

3. Deficiencies of concentration, persistence or pace resulting in frequent failure to complete tasks in a timely manner (in work settings or elsewhere); or

4. Repeated episodes of deterioration or decompensation in work or work-like settings which cause the individual to withdraw from that situation or to experience exacerbation of signs and symptoms (which may include deterioration of adaptive behaviors).

Or

C. Resulting in complete inability to function independently outside the area of one's home.

12.07 *Somatoform Disorders:* Physical symptoms for which there are no demonstrable organic findings or known physiological mechanisms.

The required level of severity for these disorders is met when the requirements in both A and B are satisfied.

A. Medically documented by evidence of one of the following:

1. A history of multiple physical symptoms of several years duration, beginning before age 30, that have caused the individual to take medicine frequently, see a physician often and alter life patterns significantly; or

2. Persistent nonorganic disturbance of one of the following:

a. Vision; or

b. Speech; or

c. Hearing; or

d. Use of a limb; or

e. Movement and its control (e.g. coordination disturbance, psychogenic seizures, akinesia, dyskinesia); or

f. Sensation (e.g., diminished or heightened).

3. Unrealistic interpretation of physical signs or sensations associated with the preoccupation or belief that one has a serious disease or injury.

And

B. Resulting in at least three of the following:

1. Marked restriction of activities of daily living; or

2. Marked difficulties in maintaining social functioning; or

3. Deficiencies of concentration, persistence or pace resulting in frequent failure to complete tasks in a timely manner (in work settings or elsewhere); or

4. Repeated episodes of deterioration or decompensation in work or work-like settings which cause the individual to withdraw from that situation or to experience exacerbation of signs and symptoms (which may include deterioration of adaptive behavior).

12.08 *Personality Disorders:* A personality disorder exists when personality traits are inflexible and maladaptive and cause either significant impairment in social or occupational functioning or subjective distress. Characteristic features are typical of the individual's long-term functioning and are not limited to discrete episodes of illness.

The required level of severity for these disorders is met when the requirements in both A and B are satisfied.

A. Deeply ingrained, maladaptive patterns of behavior associated with one of the following:

1. Seclusiveness or autistic thinking; or

2. Pathologically inappropriate suspiciousness or hostility; or

3. Oddities of thought, perception, speech and behavior; or

4. Persistent disturbances of mood or affect; or

5. Pathological dependence, passivity, or aggressivity; or

6. Intense and unstable interpersonal relationships and impulsive and damaging behavior;

And

B. Resulting in at least three of the following:

1. Marked restriction of activities of daily living; or

2. Marked difficulties in maintaining social functioning; or

3. Deficiencies of concentration, persistence or pace resulting in frequent failure to complete tasks in a timely manner (in work settings or elsewhere); or

4. Repeated episodes of deterioration or decompensation in work or work-like settings which cause the individual to withdraw from that situation or to experience exacerbation of signs and symptoms (which may include deterioration of adaptive behaviors).

12.09 *Substance Addiction Disorders:* Behavioral changes or physical changes associated with the regular use of substances that affect the central nervous system.

The required level of severity for these disorders is met when the requirements in any of the following (A through I) are satisfied.

A. Organic mental disorders. Evaluate under 12.02

B. Depressive syndrome. Evaluate under 12.04

C. Anxiety disorders. Evaluate under 12.06

D. Personality disorders. Evaluate under 12.08

E. Peripheral neuropathies. Evaluate under 11.14

F. Liver damage. Evaluate under 5.05

G. Gastritis. Evaluate under 5.04

H. Pancreatitis. Evaluate under 5.08

I. Seizures. Evaluate under 11.02 or 11.03.

13.00 Neoplastic Diseases, Malignant

A. *Introduction:* The determination or the level of impairment resulting from malignant tumors is made from a consideration of the site of the lesion, the histogenesis of the tumor, the extent of involvement, the apparent adequacy and response to therapy (surgery, irradiation, hormones, chemotherapy, etc.), and the magnitude of the post-therapeutic residuals.

B. *Documentation:* The diagnosis of malignant tumors should be established on the basis of symptoms, signs, and laboratory findings. The site of the primary, recurrent, and metastatic lesion must be specified in all cases of malignant neoplastic diseases. If an operative procedure has been performed, the evidence should include a copy of the operative note and the report of the gross and microscopic examination of the surgical specimen. If these documents are not obtainable, then the summary of hospitalization or a report from the treating physician must include details of the findings at surgery and the results of the pathologist's gross and microscopic examination or the tissues.

For those cases in which a disabling impairment was not established when therapy was begun but progression of the disease is likely, current medical evidence should include a report of recent examination directed especially at local or regional recurrence, soft part or skeletal metastases, and significant post-therapeutic residuals.

C. *Evaluation:* Usually, when the malignant tumor consists only of a local lesion with metastases to the regional lymph nodes which apparently has been completely excised, imminent recurrence or metastases is not anticipated. A number of exceptions are noted in the specific listings. For adjudicative purposes, "distant metastases" or "metastases beyond the regional lymph nodes" refers to metastases beyond the lines of the usual radical en bloc resection.

Local or regional recurrence after radical surgery or pathological evidence of incomplete excision by radical surgery is to be equated with unresectable lesions (except for carcinoma of the breast, 13.09C) and, for the purposes of our program, may be evaluated as "inoperable."

Local or regional recurrence after incomplete excision of a localized and still completely resectable tumor is not to be equated with recurrence after radical surgery. In the evaluation of lymphomas, the tissue type and site of involvement are not necessarily indicators of the degree of impairment.

When a malignant tumor has metastasized beyond the regional lymph nodes, the impairment will usually be found to meet the requirements of a specific listing. Exceptions are hormone-dependent tumors, isotope-sensitive metastases, and metastases from seminoma of the testicles which are controlled by definitive therapy.

When the original tumor and any metastases have apparently disappeared and have not been evident for 3 or more years, the impairment does not meet the criteria under this body system.

D. *Effects of Therapy.* Significant post-therapeutic residuals, not specifically included in the category of impairments for malignant neoplasms, should be evaluated according to the affected body system.

Where the impairment is not listed in the Listing of Impairments and is not medically equivalent to a listed impairment, the impact of any residual impairment including that caused by therapy must be considered. The therapeutic regimen and consequent adverse response to therapy may vary widely; therefore, each case must be considered on an individual basis. It is essential to obtain a specific description of the therapeutic regimen, including the drugs given, dosage, frequency of drug administration, and plans for

continued drug administration. It is necessary to obtain a description of the complications or any other adverse response to therapy such as nausea, vomiting, diarrhea, weakness, dermatologic disorders, or reactive mental disorders. Since the severity of the adverse effects of anticancer chemotherapy may change during the period of drug administration, the decision regarding the impact of drug therapy should be based on a sufficient period of therapy to permit proper consideration.

E. *Onset.* To establish onset of disability prior to the time a malignancy is first demonstrated to be inoperable or beyond control by other modes of therapy (and prior evidence is nonexistent) requires medical judgment based on medically reported symptoms, the type of the specific malignancy, its location, and extent of involvement when first demonstrated.

13.01 Category of Impairments, Neoplastic Diseases, Malignant

13.02 Head *and Neck* (except salivary glands - 13.07, thyroid gland - 13.08, and mandible, maxilla, orbit, or temporal fossa - 13.11):

A. Inoperable; or

B. Not controlled by prescribed therapy; or

C. Recurrent after radical surgery or irradiation; or

D. With distant metastases; or

E. Epidermoid carcinoma occurring in the pyriform sinus or posterior third of the tongue.

13.03 *Sarcoma of Skin:*

A. Angiosarcoma with metastases to regional lymph nodes or beyond; or

B. Mycosis fungoides with metastases to regional lymph nodes, or with visceral involvement.

13.04 *Sarcoma of Soft Parts: Not controlled by prescribed therapy*.

13.05 *Malignant Melanoma:*

A. Recurrent after wide excision; or

B. With metastases to adjacent skin (satellite lesions) or elsewhere.

13.06 *Lymph Nodes:*

A. Hodgkin's disease or non-Hodgkin's lymphoma with progressive disease not controlled by prescribed therapy; or

B. Metastatic carcinoma in a lymph node (except for epidermoid carcinoma in a lymph node in the neck) where the primary site is not determined after adequate search; or

C. Epidermoid carcinoma in a lymph node in the neck not responding to prescribed therapy.

13.07 *Salivary glands* - carcinoma or sarcoma with metastases beyond the regional lymph nodes.

13.08 *Thyroid Gland* - Carcinoma with metastases beyond the regional lymph nodes, not controlled by prescribed therapy.

13.09 *Breast:*

A. Inoperable carcinoma; or

B. Inflammatory carcinoma; or

C. Recurrent carcinoma, except local recurrence controlled by prescribed therapy; or

D. Distant metastases from breast carcinoma (bilateral breast carcinoma, synchronous or metachronous, is usually primary in each breast); or

E. Sarcoma with metastases anywhere.

13.10 *Skeletal System* (exclusive of the jaw):

A. Malignant primary tumors with evidence of metastases and not controlled by prescribed therapy; or

B. Metastatic carcinoma to bone where the primary site is not determined after adequate search.

13.11 *Mandible, maxilla, orbit, or temporal fossa:*

A. Sarcoma of any type with metastases; or

B. Carcinoma of the antrum with extension into the orbit or ethmoid or sphenoid sinus, or with regional or distant metastases; or

C. Orbital tumors with intracranial extension; or

D. Tumors of the temporal fossa with perforation of skull and meningeal involvement; or

E. Adamantinoma with orbital or intracranial infiltration; or

F. Tumors of Rathke's pouch with infiltration of the base of the skull or metastases.

13.12 *Brain or Spinal Cord:*

A. Metastatic carcinoma to brain or spinal cord.

B. Evaluate other tumors under the criteria described in 11.05 and 11.08.

13.13 *Lungs:*

A. Unresectable or with incomplete excision; or

B. Recurrence or metastases after resection; or

C. Oat cell (small cell) carcinoma; or

D. Squamous cell carcinoma, with metastases beyond the hilar lymph nodes; or

E. Other histologic types of carcinoma, including undifferentiated and mixed-cell types (but excluding oat cell carcinoma, 13.13C, and squamous cell carcinoma, 13.13D), with metastases to the hilar lymph nodes.

13.14 *Pleura or Mediastinum:*

A. Malignant mesothelioma of pleura; or

B. Malignant tumors, metastatic to pleura; or

C. Malignant primary tumor of the mediastinum not controlled by prescribed therapy.

13.15 *Abdomen:*

A. Generalized carcinomatosis; or

B. Retroperitoneal cellular sarcoma not controlled by prescribed therapy; or

C. Ascites with demonstrated malignant cells.

13.16 *Esophagus or stomach:*

A. Carcinoma or sarcoma of the esophagus; or

B. Carcinoma of the stomach with metastases to the regional lymph nodes or extension to surrounding structures; or

C. Sarcoma or stomach not controlled by prescribed therapy; or

D. Inoperable carcinoma; or

E. Recurrence or metastasis after resection.

13.17 *Small intestine:*

A. Carcinoma, sarcoma, or carcinoid tumor with metastases beyond the regional lymph nodes; or

B. Recurrence of carcinoma, sarcoma, or carcinoid tumor after resection; or

C. Sarcoma, not controlled by prescribed therapy.

13.18 *Large intestine (from ileocecal valve to and including anal canal) - carcinoma or sarcoma:*

A. Unresectable; or

B. Metastases beyond the regional lymph nodes; or

C. Recurrence or metastases after resection.

13.19 *Liver or Gallbladder:*

A. Primary or metastatic malignant tumors of the liver; or

B. Carcinoma of the gallbladder; or

C. Carcinoma of the bile ducts.

13.20 *Pancreas:*

A. Carcinoma except islet cell carcinoma; or

B. Islet cell carcinoma which is unresectable and physiologically active.

13.21 *Kidneys, Adrenal Glands, or Ureters - Carcinoma:*

A. Unresectable; or

B. With Hematogenous spread to distant sites; or

C. With metastases to regional lymph nodes.

13.22 *Urinary bladder - carcinoma.* With:

A. Infiltration beyond the bladder wall; or

B. Metastases to regional lymph nodes; or

C. Unresectable; or

D. Recurrence after total cystectomy; or

E. Evaluate renal impairment after total cystectomy under the criteria in 6.02

13.23 *Prostate gland* - carcinoma not controlled by prescribed therapy.

13.24 *Testicles:*

A. Choriocarcinoma; or

B. Other malignant primary tumors with progressive disease not controlled by prescribed therapy.

13.25 *Uterus* - carcinoma or sarcoma (corpus or cervix):

A. Inoperable and not controlled by prescribed therapy; or

B. Recurrent after total hysterectomy; or

C. Total pelvic exenteration.

13.26 *Ovaries* - all malignant primary or recurrent tumors. With:

A. Ascites with demonstrated malignant cells; or

B. Unresectable infiltration; or

C. Unresectable metastases to omentum or elsewhere in the peritoneal cavity; or

D. Distant metastases.

13.27 *Leukemia:* Evaluate under the criteria of 7.00ff, Hemic and Lymphatic System.

13.28 *Uterine (Fallopian) Tubes - carcinoma or sarcoma:*

A. Unresectable; or

B. Metastases to regional lymph nodes.

13.29 *Penis - carcinoma, with metastases to regional lymph nodes.*

13.30 *Vulva - carcinoma, with distant metastases.*

14.00 Immune System

A. Listed disorders include impairments involving deficiency of one or more components of the immune system (i.e., antibody-producing B cells; a number of different types of cells associated with cell-mediated immunity including T-lymphocytes, macrophages and monocytes; and components of the complement system).

B. Dysregulation of the immune system may result in the development of a connective tissue disorder. Connective tissue disorders include several chronic multisystem disorders that differ in their clinical manifestation, course, and outcome. They generally evolve and persist for months or years, may result in loss of functional abilities, and may require long-term, repeated evaluation and management.

The documentation needed to establish the existence of a connective tissue disorder is medical history, physical examination, selected laboratory studies, medically acceptable imaging techniques and, in some instances, tissue biopsy. However, the Social Security Administration will not purchase diagnostic tests or procedures that may involve significant risk, such as biopsies or angiograms. Generally, the existing medical evidence will contain this information.

A longitudinal clinical record of at least 3 months demonstrating active disease despite prescribed treatment during this period with the expectation that the disease will remain active for 12 months is necessary for assessment of severity and duration of impairment.

To permit appropriate application of a listing, the specific diagnostic features that should be documented in the clinical record for each of the disorders are summarized for systemic lupus erythematosus (SLE), systemic vasculitis, systemic sclerosis and scleroderma, polymyositis or dermatomyositis, and undifferentiated connective tissue disorders.

In addition to the limitations caused by the connective tissue disorder *per se*, the chronic adverse effects of treatment (e.g., corticosteroid-related ischemic necrosis of bone) may result in functional loss.

These disorders may preclude performance of any gainful activity by reason of severe loss of function in a single organ or body system, or lesser degrees of functional loss in two or more organs/body systems associated with significant constitutional symptoms and signs of severe fatigue, fever, malaise, and weight loss. We use the term 'severe' in these listings to describe medical severity; the term does not have the same meaning as it does when we use it in connection with a finding at the second step of the sequential evaluation processes in Sections 404.1520, 416.920, and 416.924.

1. Systemic lupus erythematosus (14.02) - This disease is characterized clinically by constitutional symptoms and signs (e.g., fever, fatigability, malaise, weight loss), multisystem involvement, and frequently, anemia, leukopenia, or thrombocytopenia. Immunologically, an array of circulating serum auto-antibodies can occur, but are highly variable in pattern. Generally the medical evidence will show that patients with this disease will fulfill The 1982 Revised Criteria for the Classification of Systemic Lupus Erythematosus of the American College of Rheumatology. (Tan, E.M., et al., Arthritis Rheum. 25:11271-1277, 1982).

2. Systemic vasculitis (14.03) - This disease occurs acutely in association with adverse drug reactions, certain chronic infections and, occasionally, malignancies. More often it is idiopathic and chronic. There are several clinical patterns, including classical polyarteritis nodosa, aortic arch arteritis, giant cell arteritis, Wegener's granulomatosis, and vasculitis associated with other connective tissue disorders (e.g., rheumatoid arthritis, SLE, Sjögren's syndrome, cryoglobulinemia). Cutaneous vasculitis may or may not be associated with systemic involvement and the patterns of vascular and ischemic involvement are highly variable. The diagnosis is confirmed by angiography or tissue biopsy when the disease is suspected clinically. Most patients who are stated to have this disease will have the results of the confirmatory angiogram or biopsy in their medical records.

3. Systemic sclerosis and scleroderma (14.04) - These disorders constitute a spectrum of disease in which thickening of the skin is the clinical hallmark. Raynaud's phenomena, often severe and progressive, are especially frequent and may be the peripheral manifestation of a generalized vasospastic abnormality in the heart, lungs, and kidneys. The CREST syndrome (calcinosis, Raynaud's phenomena, esophageal dysmotility, sclerodactyly, talangiectasia) is a variant that may slowly progress to the generalized process, systemic sclerosis, over years. In addition to skin and blood vessels, the major organ/body system involvement includes the gastrointestinal tract, lungs, heart, kidneys, and muscle. Although arthritis can occur, joint dysfunction results primarily from soft tissue/cutaneous thickening, fibrosis, and contractures.

4. Polymyositis or dermatomyositis (14.05) - This disorder is primarily an inflammatory process in striated muscle, which can occur alone or in association with other connective tissue disorders or malignancy. Weakness and less frequently, pain and tenderness of the proximal limb-girdle musculature are the cardinal manifestations. Involvement of the cervical muscles, the cricopharyngeals, the intercostals, and diaphragm may occur in those with listing-level disease.

Weakness of the pelvic girdle, as contemplated in Listing 14.05.A, may result in significant difficulty climbing stairs or rising from a chair without use of the arms. Proximal limb weakness in the upper extremities may result in inability to lift objects, and interference with dressing and combing hair. Weakness of anterior neck flexors may impair the ability to lift the head from the pillow in bed. The diagnosis is supported by elevated serum muscle enzymes (creatine phosphokinase (CPK), aminotransferases, aldolase), characteristic abnormalities on electromyography, and myositis on muscle biopsy.

5. Undifferentiated connective tissue disorder (14.06) - This listing includes syndromes with clinical and immunologic features of several connective tissue disorders, but that do not satisfy the criteria for any of the disorders described; for instance, the individual may have clinical features of systemic lupus erythematosus and systemic vasculitis and the serologic findings of rheumatoid arthritis. It also includes overlap syndromes with clinical features of more than one established connective tissue disorder. For example, the individual may have features of both rheumatoid arthritis and scleroderma. The correct designation of this disorder is important for assessment of prognosis.

C. Allergic disorders (e.g., asthma or atopic dermatitis) are discussed and evaluated under the appropriate listing of the affected body system.

D. Human immunodeficiency virus (HIV) infection.

1. HIV infection is caused by a specific retrovirus and may be characterized by susceptibility to one or more opportunistic diseases, cancers, or other conditions, as described in 14.08. Any individual with HIV infection, including one with a diagnosis of acquired immunodeficiency syndrome (AIDS), may be found disabled under this listing if his or her impairment meets any of the criteria in 14.08 or is of equivalent severity to any impairment in 14.08.

2. Definitions. In 14.08, the terms “resistant to treatment,” “recurrent,” and “disseminated” have the same general meaning as used by the medical community. The precise meaning of any of these terms will depend upon the specific disease or condition in question, the body system affected, the usual course of the disorder and its treatment, and the other circumstances of the case.

“Resistant to treatment” means that a condition did not respond adequately to an appropriate course of treatment. Whether a response is adequate, or a course of treatment appropriate, will depend on the facts of the particular case.

“Recurrent” means that a condition that responded adequately to an appropriate course of treatment has returned after a period of remission or regression. The extent of response (or remission) and the time periods involved will depend on the facts of the particular case.

"Disseminated" means that a condition is spread widely over a considerable area or body system(s). The type and extent of the spread will depend on the specific disease.

As used in 14.08I, "significant involuntary weight loss" does not correspond to a specific minimum amount or percentage of weight loss. Although, for purposes of this listing, an involuntary weight loss of at least 10 percent of baseline is always considered significant, loss of less than 10 percent may or may not be significant, depending on the individual's baseline weight and body habitus. (For example, a 7-pound weight loss in a 100-pound female who is 63 inches tall might be considered significant; but a 14- pound weight loss in a 200-pound female who is the same height might not be significant.)

3. Documentation of HIV infection. The medical evidence must include documentation of HIV infection. Documentation may be by laboratory evidence or by other generally acceptable methods consistent with the prevailing state of medical knowledge and clinical practice.

a. Documentation of HIV infection by definitive diagnosis. A definitive diagnosis of HIV infection is documented by one or more of the following laboratory tests:

i] A serum specimen that contains HIV antibodies. HIV antibodies are usually detected by a screening test. The most commonly used screening test is the ELISA. Although this test is highly sensitive, it may yield false positive results. Therefore, positive results from an ELISA must be confirmed by a more definitive test (e.g., Western Blot, immunofluorescence assay).

ii] A specimen that contains HIV antigen (e.g., serum specimen, lymphocyte culture, or cerebrospinal fluid (CFS) specimen).

iii] Other test(s) that are highly specific for detection of HIV (e.g., polymerase chain reaction (PCR)), or that are acceptable methods of detection consistent with the prevailing state of medical knowledge.

When laboratory testing for HIV infection has been performed, every reasonable effort must be made to obtain reports of the results of that testing.

Individuals who have HIV infection or other disorders of the immune system may undergo tests to determine T-helper lymphocyte (CD4) counts. The extent of immune depression correlates with the level or rate of decline of the CD4 count. In general, when the CD4 count is 200/mm^3 or less (14 percent or less), the susceptibility to opportunistic disease is considerably increased. However, a reduced CD4 count alone does not establish a definitive diagnosis of HIV infection, or document the severity or functional effects of HIV infection.

b. Other acceptable documentation of HIV infection.

HIV infection may also be documented without the definitive laboratory evidence described in paragraph a, provided that such documentation is consistent with the prevailing state of medical knowledge and clinical practice and is consistent with the other evidence. If no definitive laboratory evidence is available, HIV infection may be documented by the medical history, clinical and laboratory findings, and diagnosis(es) indicated in the medical evidence. For example, a diagnosis of HIV infection will be accepted without definitive

laboratory evidence if the individual has an opportunistic disease (e.g., toxoplasmosis of the brain, pneumocystis carinii pneumonia (PCP)) predictive of a defect in cell-mediated immunity, and there is no other known cause of diminished resistance to that disease (e.g., long-term steroid treatment, lymphoma). In such cases, every reasonable effort must be made to obtain full details of the history, medical findings, and results of testing.

4. Documentation of the manifestations of HIV infection. The medical evidence must also include documentation of the manifestations of HIV infection. Documentation may be by laboratory evidence or by other generally acceptable methods consistent with the prevailing state of medical knowledge and clinical practice.

a. Documentation of the manifestations of HIV infection by definitive diagnosis.

The definitive method of diagnosing opportunistic diseases or conditions that are manifestations of HIV infection is by culture, serological test, or microscopic examination of biopsied tissue or other material (e.g., bronchial washings). Therefore, every reasonable effort must be made to obtain specific laboratory evidence of an opportunistic disease or other condition whenever this information is available. If a histological or other test has been performed, the evidence should include a copy of the appropriate report. If the report is not obtainable, the summary of hospitalization or a report from the treating source should include details of the findings and results of the diagnostic studies (including radiographic studies) or microscopic examination of the appropriate tissues or body fluids.

Although a reduced CD4 lymphocyte count may show that there is an increased susceptibility to opportunistic infections and diseases (see 14.00D 3a, above), that alone does not establish the presence, severity, or functional effects of a manifestation of HIV infection.

b. Other acceptable documentation of the manifestations of HIV infection.

Manifestations of HIV infection may also be documented without the definitive laboratory evidence described in paragraph a, provided that such documentation is consistent with the prevailing state of medical knowledge and clinical practice and is consistent with the other evidence. If no definitive laboratory evidence is available, manifestations of HIV infection may be documented by medical history, clinical and laboratory findings, and diagnosis(es) indicated in the medical evidence. In such cases, every reasonable effort must be made to obtain full details of the history, medical findings, and results of testing.

Documentation of cytomegalovirus (CMV) disease (14.08D) presents special problems because diagnosis requires identification of viral inclusion bodies or a positive culture from the affected organ, and the absence of any other infectious agent. A positive serology test identifies infection with the virus, but does not confirm a disease process. With the exception of chorioretinitis (which may be diagnosed by an ophthalmologist), documentation of CMV disease requires confirmation by biopsy or other generally acceptable methods consistent with the prevailing state of medical knowledge and clinical practice.

5. Manifestations specific to women. Most women with severe immunosuppression secondary to HIV infection exhibit the typical opportunistic infections and other conditions, such as pneumocystis carinii pneumonia (PCP), candida esophagitis, wasting syndrome, cryptococcosis, and toxoplasmosis. However HIV infection may have different manifestations in women than in men. Adjudicators must carefully scrutinize the medical evidence and be alert to the variety of medical conditions specific to or common in women with HIV infection that may affect their ability to function in the workplace.

Many of these manifestations (e.g., vulvovaginal candidiasis, pelvic inflammatory disease) occur in women with or without HIV infection, but can be more severe or resistant to treatment, or occur more frequently in a woman whose immune system is suppressed. Therefore, when evaluating the claim of a woman with HIV infection, it is important to consider gynecologic and other problems specific to women, including any associated symptoms (e.g., pelvic pain), in assessing the severity of the impairment and resulting functional limitations. Manifestations of HIV infection in women may be evaluated under the specific criteria (e.g., cervical cancer under 14.08E), under an applicable general category (e.g., pelvic inflammatory disease under 14.08A5) or, in appropriate cases, under 14.08N.

6. Evaluation. The criteria in 14.08 do not describe the full spectrum of diseases or conditions manifested by individuals with HIV infection. As in any case, consideration must be given to whether an individual's impairment(s) meets or equals in severity any other listing in appendix 1 of subpart P (e.g., a neoplastic disorder listed in 13.00ff). Although 14.08 includes cross-references to other listings for the more common manifestations of HIV infection, other listings may apply.

In addition, the impact of all impairments, whether or not related to HIV infection, must be considered. For example, individuals with HIV infection may manifest signs and symptoms of a mental impairment (e.g., anxiety, depression), or of another physical impairment. Medical evidence should include documentation of all physical and mental impairments, and the impairment(s) should be evaluated not only under the relevant listing(s) in 14.08, but under any other appropriate listing(s).

It is also important to remember that individuals with HIV infection, like all other individuals, are evaluated under the full five-step sequential evaluation process described in Section 404.1520 and Section 416.920. If an individual with HIV infection is working and engaging in substantial gainful activity (SGA), or does not have a severe impairment, the case will be decided at the first or second step of the sequential evaluation process, and does not require evaluation under these listings. For an individual with HIV infection who is not engaging in SGA and has a severe impairment, but whose impairment(s) does not meet or equal in severity the criteria of a listing, evaluation must proceed through the final steps of the sequential evaluation process (or, as appropriate, the steps in the medical improvement review standard) before any conclusion can be reached on the issue of disability.

7. Effect of treatment. Medical treatment must be considered in terms of its effectiveness in ameliorating the signs, symptoms, and laboratory abnormalities of the specific disorder, or of the HIV infection itself (e.g. antiretroviral agents)

and in terms of any side effects of treatment that may further impair the individual.

Response to treatment and adverse or beneficial consequences of treatment may vary widely. For example, an individual with HIV infection who develops pneumonia or tuberculosis may respond to the same antibiotic regimen used in treating individuals without HIV infection, but another individual with HIV infection may not respond to the same regimen. Therefore, each case must be considered on an individual basis, along with the effects of treatment on the individual's ability to function.

A specific description of the drugs or treatment given (including surgery), dosage, frequency of administration, and a description of the complications or response to treatment should be obtained. The effects of treatment may be temporary or long term. As such, the decision regarding the impact of treatment should be based on a sufficient period of treatment to permit proper consideration.

8. Functional criteria. Paragraph N of 14.08 establishes standards for evaluating manifestations of HIV infection that do not meet the requirements listed in 14.08A-M. Paragraph N is applicable for manifestations that are not listed in 14.08A-M, as well as those listed in 14.08A-M that do not meet the criteria of any of the rules in 14.08A-M.

For individuals with HIV infection evaluated under 14.08N, listing-level severity will be assessed in terms of the functional limitations imposed by the impairment. The full impact of signs, symptoms, and laboratory findings on the claimant's ability to function must be considered. Important factors to be considered in evaluating the functioning of individuals with HIV infection include, but are not limited to: symptoms, such as fatigue and pain; characteristics of the illness, such as the frequency and duration of manifestations or periods of exacerbation and remission in the disease course; and the functional impact of treatment for the disease, including the side effects of medication.

As used in 14.08N, "repeated" means that the conditions occur on an average of 3 times a year, or once every 4 months, each lasting 2 weeks or more; or the conditions do not last for 2 weeks but occur substantially more frequently than 3 times in a year or once every 4 months; or they occur less often than an average of 3 times a year or once every 4 months but last substantially longer than 2 weeks.

To meet the criteria in 14.08N, an individual with HIV infection must demonstrate a marked level of restriction in one of three general areas of functioning: activities of daily living; social functioning; and difficulties in completing tasks due to deficiencies in concentration, persistence, or pace. Functional restrictions may result from the impact of the disease process itself on mental or physical functioning, or both. This could result from extended or intermittent symptoms, such as depression, fatigue, or pain, resulting in a limitation of the ability to concentrate, to persevere at a task, or to perform the task at an acceptable rate of speed. Limitations may also result from the side effects of medication.

When “marked” is used as a standard for measuring the degree of functional limitation, it means more than moderate, but less than extreme. A marked limitation does not represent a quantitative measure of the individual’s ability to do an activity for a certain percentage of the time. A marked limitation may be present when several activities or functions are impaired or even when only one is impaired. However, an individual need not be totally precluded from performing an activity to have a marked limitation, as long as the degree of limitation is such as to seriously interfere with the ability to function independently, appropriately, and effectively. The term “marked” does not imply that the impaired individual is confined to bed, hospitalized, or in a nursing home.

Activities of daily living include, but are not limited to, such activities as doing household chores, grooming and hygiene, using a post office, taking public transportation, and paying bills. An individual with HIV infection who, because of symptoms such as pain imposed by the illness or its treatment, is not able to maintain a household or take public transportation on a sustained basis or without assistance (even though he or she is able to perform some self-care activities) would have marked limitation of actives of daily living.

Social functioning includes the capacity to interact appropriately and communicate effectively with others. An individual with HIV infection who, because of symptoms or a pattern of exacerbation and remission caused by the illness or its treatment, cannot engage in social interaction on a sustained basis (even though he or she is able to communicate with close friends or relatives) would have marked difficulty maintaining social functioning.

Completing tasks in a timely manner involves the ability to sustain concentration, persistence, or pace to permit timely completion of tasks commonly found in work settings. An individual with HIV infection who, because of HIV-related fatigue or other symptoms, is unable to sustain concentration or pace adequate to complete simple work-related tasks (even though he or she is able to do routine activities of daily living) would have marked difficulty completing tasks.

14.01 *Category of Impairments, Immune System*

14.02 *Systemic lupus erythematosus.* Documented as described in 14.00B1, with:

A. One of the following:

1. Joint involvement, as described under the criteria in 1.00; or

2. Muscle involvement, as described under the criteria in 14.05; or

3. Ocular involvement, as described under the criteria in 2.00ff; or

4. Respiratory involvement, as described under the criteria in 3.00ff; or

5. Cardiovascular involvement, as described under the criteria in 4.00ff or 14.04D; or

6. Digestive involvement, as described under the criteria in 5.00ff; or

7. Renal involvement, as described under the criteria in 6.00ff; or

8. Skin involvement, as described under the criteria in 8.00ff; or

9. Neurological involvement, as described under the criteria in 11.00ff; or

10. Mental involvement, as described under the criteria in 12.00ff.

Or

B. Lesser involvement of two or more organs/body systems listed in paragraph A, with significant, documented, constitutional symptoms and signs of severe fatigue, fever, malaise, and weight loss. At least one of the organs/body systems must be involved to at least a moderate level of severity.

14.03 *Systemic vasculitis*. Documented as described in 14.00B2, including documentation by angiography or tissue biopsy, with:

A. Involvement of a single organ or body system, as described under the criteria in 14.02A.

Or

B. Lesser involvement of two or more organs/body systems listed in 14.02A, with significant, documented, constitutional symptoms and signs of severe fatigue, fever, malaise, and weight loss. At least one of the organs/body systems must be involved to at least a moderate level of severity.

14.04 *Systemic sclerosis and scleroderma.* Documented as described in 14.00B3, with:

A. One of the following:

1. Muscle involvement, as described under the criteria in 14.05; or

2. Respiratory involvement, as described under the criteria in 3.00ff; or

3. Cardiovascular involvement, as described under the criteria in 4.00ff; or

4. Digestive involvement, as described under the criteria in 5.00ff; or

5. Renal involvement, as described under the criteria in 6.00ff.

Or

B. Lesser involvement of two or more organs/body systems listed in paragraph A, with significant, documented, constitutional symptoms and signs of severe fatigue, fever, malaise, and weight loss. At least one of the organs/body systems must be involved to at least a moderate level of severity.

Or

C. Generalized scleroderma with digital contractures.

Or

D. Severe Raynaud's phenomena, characterized by digital ulcerations, ischemia, or gangrene.

14.05 *Polymyositis or dermatomyositis.* Documented as described in 14.00B4, with:

A. Severe proximal limb-girdle (shoulder and/or pelvic) muscle weakness, as described in 14.08B4.

Or

B. Less severe limb-girdle muscle weakness than in 14.05A, associated with cervical muscle weakness and one of the following to at least a moderate level of severity:

1. Impaired swallowing with dysphagia and episodes of aspiration due to cricopharyngeal weakness, or

2. Impaired respiration due to intercostal and diaphragmatic muscle weakness.

Or

C. If associated with malignant tumor, as described under the criteria in 13.00ff.

Or

D. If associated with generalized connective tissue disease, as described under the criteria in 14.02, 14.03, 14.04, or 14.06.

14.06 *Undifferentiated connective tissue disorder.* Documented as described in 14.00B5, and with impairment as described under the criteria in 14.02A, 14.02B, or 14.04.

14.07 *Immunoglobulin deficiency syndromes or deficiencies of cell-mediated immunity, excepting HIV infection.* Associated with documented, recurrent severe infection occurring 3 or more times within a 5-month period.

14.08 *Human Immunodeficiency Virus (HIV) infection.* With documentation as described in 14.00D3 and one of the following:

A. Bacterial infections:

1. Mycobacterial infection (e.g., caused by M. avium-intracellulare, M. kansasii, or M. tuberculosis) at site other than the lungs, skin, or cervical or hilar lymph nodes; or pulmonary tuberculosis resistant to treatment; or

2. Nocardiosis; or

3. Salmonella bacteremia, recurrent non-typhoid; or

4. Syphilis or neurosyphilis - evaluate sequelae under the criteria for the affected body system (e.g., 2.00 Special Senses and Speech, 4.00 Cardiovascular System, 11.00 Neurological); or

5. Multiple or recurrent bacterial infection(s), including pelvic inflammatory disease, requiring hospitalization or intravenous antibiotic treatment 3 or more times in 1 year.

Or

B. Fungal infections:

1. Aspergillosis; or

2. Candidiasis, at a site other than the skin, urinary tract, intestinal tract, or oral or vulvovaginal mucous membranes; or candidiasis involving the esophagus, trachea, bronchi, or lungs; or

3. Coccidioidomycosis, at a site other than the lungs or lymph nodes; or

4. Cryptococcosis, at a site other than the lungs (e.g., cryptococcal meningitis); or

5. Histoplasmosis, at a site other than the lungs or lymph nodes; or

6. Mucormycosis.

Or

C. Protozoan or helminthic infections:

1. Cryptosporidiosis, isosporiasis, or microsporidiosis, with diarrhea lasting for 1 month or longer; or

2. Pneumocystis carinii pneumonia or extrapulmonary pneumocystis carinii infection; or

3. Strongyloidiasis, extra-intestinal; or

4. Toxoplasmosis of an organ other then the liver, spleen, or lymph nodes.

Or

D. Viral infections:

1. Cytomegalovirus disease (documented as described in 14.00D4b) at a site other than the liver, spleen, or lymph nodes; or

2. Herpes simplex virus causing:

a. Mucocutaneous infection (e.g., oral, genital, perianal) lasting for 1 month or longer; or

b. Infection at a site other than the skin or mucous membranes (e.g., bronchitis, pneumonitis, esophagitis, or encephalitis); or

c. Disseminated infection; or

3. Herpes zoster, either disseminated or with multidermatomal eruptions that are resistant to treatment; or

4. Progressive multifocal leukoencephalopathy; or

5. Hepatitis, as described under the criteria in 5.05.

or

E. Malignant neoplasms:

1. Carcinoma of the cervix, invasive, FIGO stage II and beyond; or

2. Kaposi's sarcoma with:

a. Extensive oral lesions; or

b. Involvement of the gastrointestinal tract, lungs, or other visceral organs; or

c. Involvement of the skin or mucous membranes, as described under the criteria in 14.08F; or

3. Lymphoma (e.g., primary lymphoma of the brain, Burkitt's lymphoma, immunoblastic sarcoma, other non-Hodgkins lymphoma, Hodgkin's disease); or

4. Squamous cell carcinoma of the anus.

or

F. Conditions of the skin or mucous membranes (other than described in B2, D2, or D3, above), with extensive fungating or ulcerating lesions not responding to treatment (e.g., dermatological conditions such as eczema or psoriasis, vulvovaginal or other mucosal candida, condyloma caused by human papillomavirus, genital ulcerative disease), or evaluate under the criteria in 8.00ff.

or

G. Hematologic abnormalities:

1. Anemia, as described under the criteria in 7.02; or

2. Granulocytopenia, as described under the criteria in 7.15; or

3. Thrombocytopenia, as described under the criteria in 7.06.

or

H. Neurological abnormalities:

1. HIV encephalopathy, characterized by cognitive or motor dysfunction that limits function and progresses; or

2. Other neurological manifestations of HIV infection (e.g., peripheral neuropathy) as described under the criteria in 11.00ff.

Or

I. HIV wasting syndrome, characterized by involuntary weight loss of 10 percent or more of baseline (or other significant involuntary weight loss, as described in 14.00D2) and, in the absence of a concurrent illness that could explain the findings, either:

1. Chronic diarrhea with two or more loose stools daily lasting for 1 month or longer; or

2. Chronic weakness and documented fever greater than 38^{o} C (100.4^{o} F) for the majority of 1 month or longer.

Or

J. Diarrhea, lasting for 1 month or longer, resistant to treatment, and requiring intravenous hydration, intravenous alimentation, or tube feeding.

Or

K. Cardiomyopathy, as described under the criteria in 4.00ff or 11.04.

Or

L. Nephropathy, as described under the criteria in 6.00ff.

Or

M. One or more of the following infections (other than described in A-L, above), resistant to treatment or requiring hospitalization or intravenous treatment 3 or more times in 1 year (or evaluate sequelae under the criteria for the affected body system).

1. Sepsis; or

2. Meningitis; or

3. Pneumonia; or

4. Septic Arthritis; or

5. Endocarditis; or

6. Radiographically documented sinusitis.

Or

N. Repeated (as defined in 14.00D8) manifestations of HIV infection (including those listed in 14.08 A-M, but without the requisite findings, e.g., carcinoma of the cervix not meeting the criteria in 14.08E, diarrhea not meeting the criteria in 14.08J, or other manifestations, e.g., oral hairy leukoplakia, myositis) resulting in significant, documented symptoms or signs (e.g., fatigue, fever, malaise,

weight loss, pain, night sweats) and one of the following at the marked level (as defined in 14.00D8):

1. Restriction of activities of daily living; or

2. Difficulties in maintaining social functioning; or

3. Difficulties in completing tasks in a timely manner due to deficiencies in concentration, persistence, or pace.

PART B

The following sections provide medical criteria for the evaluation of impairments of children under age 18 (where criteria in Part A do not give appropriate consideration to the particular disease process in childhood).

Sec.

100.00 Growth Impairment

A. *Impairment of growth* may be disabling in itself or it may be an indicator of the severity of the impairment due to a specific disease process.

Determinations of growth impairment should be based upon the comparison of current height with at least three previous determinations, including length at birth, if available, Heights (or lengths) should be plotted on a standard growth chart, such as derived from the National Center for Health Statistics: NCHS Growth Charts. Height should be measured without shoes, Body weight corresponding to the ages represented by the heights should be furnished. The adult heights of the child's natural parents and the heights and ages of siblings should also be furnished. This will provide a basis upon which to identify those children whose short stature represents a familial characteristic rather than a result of disease. This is particularly true for adjudication under 100.02B

B. *Bone age determinations* should include a full descriptive report of roentgenograms specifically obtained to determine bone age and must cite the standardization method used. Where roentgenograms must be obtained currently as a basis for adjudication under 100.03, views of the left hand and wrist should be ordered. In addition, roentgenograms of the knee and ankle

should be obtained when cessation of growth is being evaluated in an older child at, or past, puberty.

C. The criteria in this section are applicable until closure of the major epiphyses. The cessation of significant increase in height at that point would prevent the application of these criteria.

100.01 Category of Impairments, Growth

100.02 *Growth impairment,* considered to be related to an additional specific medically determinable impairment, and one of the following:

A. Fall of greater than 15 percentiles in height which is sustained; or

B. Fall to, or persistence of, height below the third percentile.

100.03 Growth Impairment, not identified as being related to an additional, specific medically determinable impairment.

With

A. Fall of greater then 25 percentiles in height which is sustained; and

B. Bone age greater than two standard deviations (2 SD) below the mean for chronological age (see 100.00B).

101.00 Musculoskeletal System

A. *Rheumatoid arthritis.* Documentation of the diagnosis of juvenile rheumatoid arthritis should be made according to an established protocol, such as that published by the Arthritis Foundation, *Bulletin on the Rheumatic Diseases,* Vol. 23, 1972-1973 Series, p. 712. Inflammatory signs include persistent pain, tenderness, erythema, swelling, and increased local temperature of a joint.

B. *The measurements of joint motion* are based on the technique for measurements described in the "Joint Method of Measuring and Recording," published by the American Academy of Orthopedic Surgeons in 1965, or "The Extremities and Back" in "Guides to the Evaluation of Permanent Impairment," Chicago, American Medical Association, 1971, Chapter 1, pp. 1-48.

C. *Degenerative arthritis* may be the end stage of many skeletal diseases and conditions, such as traumatic arthritis, collagen disorders, septic arthritis, congenital dislocation of the hip, aseptic necrosis of the hip, slipped capital femoral epiphyses, skeletal dysplasias, etc.

101.01 Category of Impairments, Musculoskeletal

101.02 *Juvenile rheumatoid arthritis*

With:

A. Persistence or recurrence of joint inflammation despite three months of medical treatment and one of the following:

1. Limitation of motion of two major joints of 50 percent or greater; or

2. Fixed deformity of two major weight-bearing joints of 30 degrees or more; or

3. Radiographic changes of joint narrowing, erosion, or subluxation; or

4. Persistent or recurrent systemic involvement such as iridocyclitis or pericarditis; or

B. Steroid Dependence.

101.03 *Deficit of musculoskeletal function* due to deformity or musculoskeletal disease and one of the following:

A. Walking is markedly reduced in speed or distance despite orthotic or prosthetic devices; or

B. Ambulation is possible only with obligatory bilateral upper limb assistance (e.g., with walker, crutches); or

C. Inability to perform age-related personal self-care activities involving feeding, dressing, and personal hygiene.

101.05 *Disorders of the Spine.*

A. Fracture of vertebra with cord involvement (substantiated by appropriate sensory and motor loss); or

B. Scoliosis (congenital idiopathic or neuromyopathic). With:

1. Major spinal curve measuring 60 degrees or greater; or

2. Spinal fusion of six or more levels. Consider under a disability for 1 year from the time of surgery; thereafter, evaluate the residual impairment; or

3. FEV (vital capacity) of 50 percent or less of predicted normal values for the individual's measured (actual) height; or

C. Kyphosis or lordosis measuring 90 degrees or greater.

101.08 *Chronic osteomyelitis* with persistence or recurrence of inflammatory signs or drainage for at least 6 months despite prescribed therapy, and consistent radiographic findings.

102.00 Special Senses and Speech

A. Visual impairments in Children. Impairment of central visual acuity should be determined with use of the standard Snellen test chart. Where this cannot be used, as in very young children, a complete description should be provided of the findings using other appropriate methods of examination, including a description of the techniques used for determining the central visual acuity for distance.

The accommodative reflex is generally not present in children under 6 months of age. In premature infants, it may not be present until 6 months plus the number of months the child is premature. Therefore, absence of accommodative reflex will be considered as indicating a visual impairment only in children above this age (6 months).

Documentation of a visual disorder must include a description of the ocular pathology.

B. *Hearing impairments in children.* The criteria for hearing impairments in children take into account that a lesser impairment in hearing which occurs at an early age may result in a severe speech and language disorder.

Improvement by a hearing aid, as predicted by the testing procedure, must be demonstrated to be feasible in that child, since younger children may be unable to use a hearing aid effectively.

The type of audiometric testing performed must be described and a copy of the results must be included. The pure tone air conduction hearing levels in 102.08 are based on American National Standard Institute Specifications for Audiometers, S3.6 - 1969 (ANSI - 1969). The report should indicate the specifications used to calibrate the audiometer.

The finding of a severe impairment will be based on the average hearing levels at 500, 1000, 2000, and 3000 Hertz (Hz) in the better ear, and on speech discrimination, as specified in 102.08.

102.01 Category of Impairments, Special Sense Organs

102.02 *Impairments of Central Visual Acuity*

A. Remaining vision in the better eye after best correction is 20/200 or less; or

B. For children below 3 years of age at time of adjudication:

1. Absence of accommodative reflex (see 102.00A for exclusion of children under 6 months of age); or

2. Retrolental fibroplasia with macular scarring or neovascularization; or

3. Bilateral congenital cataracts with visualization of retinal red reflex only or when associated with other ocular pathology.

102.08 *Hearing Impairments*

A. For children below 5 years of age at time of adjudication, inability to hear air conduction thresholds at an average of 40 decibels (db) hearing level or greater in the better ear; or

B. For children 5 years of age and above at time of adjudication:

1. Inability to hear air conduction thresholds at an average of 70 decibels (db) or greater in the better ear; or

2. Speech discrimination scores at 40 percent or less in the better ear; or

3. Inability to hear air conduction thresholds at an average of 40 decibels (db) or greater in the better ear, and a speech and language disorder which significantly affects the clarity and content of the speech and is attributable to the hearing impairment.

103.00 Respiratory System

A. *Introduction.* The listings in this section describe impairments resulting from respiratory disorders based on symptoms, physical signs, laboratory test abnormalities, and response to a regimen of treatment prescribed by a treating source. Respiratory disorders, along with any associated impairment(s), must be established by medical evidence. Evidence must be provided in sufficient detail to permit an independent reviewer to evaluate the severity of the impairment. Reasonable efforts should be made to ensure evaluation by a program physician specializing in childhood respiratory impairments or a qualified pediatrician.

Many children, especially those who have listing-level impairments, will have received the benefit of medically prescribed treatment. Whenever there is such evidence, the longitudinal clinical record must include a description of the treatment prescribed by the treating source and response, in addition to information about the nature and severity of the impairment. It is important to document any prescribed treatment and response because this medical management may have improved the child's functional status. The longitudinal record should provide information regarding functional recovery, if any.

Some children will not have received ongoing treatment or have an ongoing relationship with the medical community, despite the existence of a severe impairment(s). A child who does not receive treatment may or may not be able to show an impairment that meets the criteria of these listings. Even if a child does not show that his or her impairment meets the criteria of these listings, the child may have an impairment(s) equivalent in severity to one of the listed impairments or be disabled because of a substantial reduction in the ability to function independently, appropriately, and effectively in an age-appropriate manner. Unless the claim can be decided favorably on the basis of the current evidence, a longitudinal record is still important because it will provide information about such things as the ongoing medical severity of the impairment, the level of the child's functioning, and the frequency, severity, and duration of symptoms. Also, the asthma listing specifically includes a requirement for continuing signs and symptoms despite a regimen of prescribed treatment.

Evaluation should include consideration of adverse effects of respiratory impairment in all relevant body systems, and especially on the child's growth and development or mental functioning, as described under the growth impairment (100.00), neurological (111.00), and mental disorders (112.00) listings.

It must be remembered that these listings are only examples of common respiratory disorders that are severe enough to prevent a child from functioning independently, appropriately and effectively in an age-appropriate manner. When a child has a medically determinable impairment that is not listed, an impairment which does not meet a listing, or a combination of impairments no one of which meets a listing, we may make an equivalence determination on medical or functional grounds. Also, with respect to children claiming SSI benefits under title XVI of the Act who have an impairment(s) with a level of severity which does not meet or equal (medically or functionally) the criteria of the listings, we will determine whether the impairment(s) is of comparable

severity to one that would disable an adult. In these cases, we will perform an individualized functional assessment to determine whether the child is disabled.

B. *Documentation of Pulmonary Function Testing*. The results of spirometry that are used for adjudication, under the 103.02 A and B, 103.03, and 103.04 of these listings should be expressed in liters (L), body temperature and pressure saturated with water vapor (BTPS). The reported one-second forced expiratory volume (FEV_1) and forced vital capacity(FVC) should represent the largest of at least three satisfactory forced expiratory maneuvers. Two of the satisfactory spirograms should be reproducible for both pre-bronchodilator tests and, if indicated, post-bronchodilator tests. A value is considered reproducible if it does not differ from the largest value by more than 5 percent or 0.1 L, whichever is greater. The highest values of the FEV_1 and FVC, whether from the same or different tracings, should be used to assess the severity of the respiratory impairment.

Peak flow should be achieved early in expiration, and the spirogram should have a smooth contour with gradually decreasing flow throughout expiration. The zero time for measurement of the FEV_1 and FVC, if not distinct, should be derived by linear back-extrapolation of peak flow to zero volume. A spirogram is satisfactory for measurement of the FEV_1 if the expiratory volume at the back-extrapolated zero time is less than 5 percent of the FVC or 0.1 L, whichever is greater. The spirogram is satisfactory for measurement of the FVC if maximal expiratory effort continues for at least 6 seconds, or if there is a plateau in the volume-time curve with no detectable change in expired volume (VE) during the last 2 seconds of maximal expiratory effort.

Spirometry should be repeated after administration of an aerosolized bronchodilator under supervision of the testing personnel if the pre-bronchodilator FEV_1 value is less than the appropriate reference value in table I or III, as appropriate. If a bronchodilator is not administered, the reason should be clearly stated in the report. Pulmonary function studies should not be performed unless the clinical status is stable (e.g., the child is not having an asthmatic attack or suffering from an acute respiratory infection or other acute illness.). Wheezing is common in asthma, chronic bronchitis, or chronic obstructive pulmonary disease and does not preclude testing. Pulmonary function studies performed to assess airflow obstruction without testing after bronchodilators cannot be used to assess levels of impairment in the range that prevents a child from performing age-appropriate activities unless the use of bronchodilators is contraindicated. Post-bronchodilator testing should be performed 10 minutes after bronchodilator administration. The dose and name of the bronchodilator administered should be specified. The values in 103.02 and 103.04 must only be used as criteria for the level of ventilatory impairment that exists during the child's most stable state of health (i.e., any period in time except during or shortly after an exacerbation).

The appropriately labeled spirometric tracing, showing the child's name, date of testing, distance per second on the abscissa and the distance per liter (L) on the ordinate, must be incorporated into the file. The manufacturer and model number of the device used to measure and record the spirogram should be stated. The testing device must accurately measure both time and volume, the latter to within 1 percent of a 3 L calibrating volume. If the spirogram was generated by

any means other than by direct pen linkage to a mechanical displacement-type spirometer, the spirometric tracing must show a recorded calibration of volume units using a mechanical volume input such as a 3 L syringe.

If the spirometer directly measures flow, and volume is derived by electronic integration, the linearity of the device must be documented by recording volume calibrations at three different flow rates of approximately 30 L/min (3 L/6 sec), 60 L/min (3 L/3 sec), and 180 L/min (3 L/sec). The volume calibrations should agree to within 1 percent of a 3 L calibrating volume. The proximity of the flow sensor to the child should be noted, and it should be stated whether or not a BTPS correction factor was used for the calibration recordings and for the child's actual spirograms.

The spirogram must be recorded at a speed of at least 20 mm/sec, and the recording device must provide a volume excursion of at least 10 mm/L. If reproductions of the original spirometric tracings are submitted, they must be legible and have a time scale of at least 20 mm/sec and a volume scale of at least 10 mm/L to permit independent measurements. Calculation of FEV_1 from a flow-volume tracing is not acceptable, i.e., the spirogram and calibrations must be presented in a volume-time format at a speed of at least 20 mm/sec and a volume excursion of at least 10 mm/L to permit independent evaluation.

A statement should be made in the pulmonary function test report of the child's ability to understand directions as well as his or her effort and cooperation in performing the pulmonary function tests.

Purchase of a pulmonary function test is appropriate only when the child is capable of performing reproducible forced expiratory maneuvers. This capability usually occurs around age 6. Purchase of a pulmonary function test may be appropriate when there is a question of whether an impairment meets or is equivalent in severity to a listing, and the claim cannot otherwise be favorably decided.

The pulmonary function tables in 103.02 and 103.04 are based on measurement of standing height without shoes. If a child has marked spinal deformities (e.g., kyphoscoliosis), the measured span between the fingertips with the upper extremities abducted 90 degrees should be substituted for height when this measurement is greater than the standing height without shoes.

C. Documentation of chronic impairment of gas exchange.

1. Arterial blood gas studies (ABGS). An ABGS performed at rest (while breathing room air, awake and sitting or standing) should be analyzed in a laboratory certified by a State or Federal agency. If the laboratory is not certified, it must submit evidence of participation in a national proficiency testing program as well as acceptable quality control at the time of testing. The report should include the altitude of the facility and the barometric pressure on the date of analysis.

Purchase of a resting ABGS may be appropriate when there is a question of whether an impairment meets or is equivalent in severity to a listing, and the claim cannot otherwise be favorably decided. Before purchasing resting ABGS, a program physician, preferably one experienced in the care of children with pulmonary disease, must review the clinical and laboratory data short of this

procedure, including spirometry, to determine whether obtaining the test would present a significant risk to the child.

2. *Oximetry.* Pulse oximetry may be substituted for arterial blood gases in children under 12 years of age. The oximetry unit should employ the basic technology of spectrophotometric plethysmography as described in Taylor, M.B., and Whitwain, J.G., "Current Status of Pulse Oximetry," "Anesthesia," Vol. 41. No. 9, pp. 943-949, 1986. The unit should provide a visual display of the pulse signal and the corresponding oxygen saturation. A hard copy of the readings (heart rate and saturation) should be provided. Readings should be obtained for a minimum of 5 minutes. The written report should describe patient activity during the recording; i.e., sleep rate, feeding, or exercise. Correlation between the actual heart rate determined by a trained observer and that displayed by the oximeter should be provided. A statement should be made in the report of the child's effort and cooperation during the test.

Purchase of oximetry may be appropriate when there is a question of whether an impairment meets or is equivalent in severity to a listing, and the claim cannot otherwise be favorably decided.

D. *Cystic fibrosis* is a disorder that affects either the respiratory or digestive body systems or both and may impact on a child's growth and development. It is responsible for a wide and variable spectrum of clinical manifestations and complications. Confirmation of the diagnosis is based upon an elevated sweat sodium concentration or chloride concentration accompanied by one or more of the following: the presence of chronic obstructive pulmonary disease, insufficiency of exocrine pancreatic function, meconium ileus, or a positive family history. The quantitative pilocarpine iontophoresis procedure for collection of sweat content must be utilized. Two methods are acceptable: the "Procedure for the Quantitative Iontophoretic Sweat Test for Cystic Fibrosis" published by the Cystic Fibrosis Foundation and contained in, "A Test for Concentration of Electrolytes in Sweat in Cystic Fibrosis of the Pancreas Utilizing Pilocarpine Iontophoresis," Gibson, I.E., and Cooke, R..E., Pediatrics, Vol. 23:545, 1959; or the "Wescor Macroduct System." To establish the diagnosis of cystic fibrosis, the sweat sodium or chloride content must be analyzed quantitatively using an acceptable laboratory technique. Another diagnostic test is the "CF gene mutation analysis" for homozygosity of the cystic fibrosis gene. The pulmonary manifestations of this disorder should be evaluated under 103.04. The nonpulmonary aspects of cystic fibrosis should be evaluated under the digestive body system (105.00) or growth impairments (100.00). Because cystic fibrosis may involve the respiratory and digestive body systems, as well as impact on a child's growth and development, the combined effects of this involvement must be considered in case adjudication.

E. *Bronchopulmonary dysplasia (BPD).* Bronchopulmonary dysplasia is a form of chronic obstructive pulmonary disease that arises as a consequence of acute lung injury in the newborn period and treatment of hyaline membrane disease, meconium aspiration, neonatal pneumonia and apnea of prematurity. The diagnosis is established by the requirement for continuous or nocturnal supplemental oxygen for more than 30 days, in association with characteristic radiographic changes and clinical signs of respiratory dysfunction, including retractions, rales, wheezing, and tachypnea.

103.01 Category of Impairments, Respiratory System.

103.02 *Chronic Pulmonary insufficiency.* With:

A. Chronic obstructive pulmonary disease due to any cause with the FEV_1 equal to or less than the value specified in Table I corresponding to the child's height without shoes. (In cases of marked spinal deformity, see 103.00B.);

Table I

Height without shoes (centimeters)	Height without shoes (inches)	FEV_1 equal to or less than (L, BTPS)
119 or less	46 or less	0.65
120–129	47–50	0.75
130–139	51-54	0.95
140–149	55–58	1.15
150–159	T59–62	1.35
160–164	63–64	1.45
165–169T	65–66	1.55
170 or more	67 or more	1.65

Or

B. Chronic restrictive ventilatory disease, due to any cause, with the FVC equal to or less then the value specified in Table II corresponding to the child's height without shoes. (In cases of marked spinal deformity, see 103.00B.);

Table II

Height without shoes (centimeters)	Height without shoes (inches)	FEV_1 equal to or less than (L, BTPS)
119 or less	46 or less	0.65
120–129	47–50	0.85
130–139	51-54	1.05
140–149	55–58	1.25
150–159	T59–62	1.45
160–164	63–64	1.65
165–169T	65–66	1.75
170 or more	67 or more	2.05

Or

C. Frequent need for:

1. Mechanical ventilation; or

2. Nocturnal supplemental oxygen as required by persistent or recurrent episodes of hypoxemia;

Or

D. The presence of a tracheostomy in a child under 3 years of age;

Or

E. Bronchopulmonary dysplasia characterized by two of the following;

1. Prolonged expirations; or

2. Intermittent wheezing or increased respiratory effort as evidenced by retractions, flaring and tachypnea; or

3. Hyperinflation and scarring on a chest radiograph or other appropriate imaging techniques; or

4. Bronchodilator or diuretic dependency; or

5. A frequent requirement for nocturnal supplemental oxygen; or

6. Weight disturbance with:

a. An involuntary weight loss (or failure to gain weight at an appropriate rate for age) resulting in a fall of 15 percentiles from established growth curve (on standard growth charts) which persists for 2 months or longer; or

b. An involuntary weight loss (or failure to gain weight at an appropriate rate for age) resulting in a fall to below the third percentile from established growth curve (on standard growth charts) which persists for 2 months or longer;

Or

F. Two required hospital admissions (each longer than 24 hours) within a 6-month period for recurrent lower respiratory tract infections or acute respiratory distress associated with:

1. Chronic wheezing or chronic respiratory distress; or

2. Weight disturbance with;

a. An involuntary weight loss (or failure to gain weight at an appropriate rate for age) resulting in a fall of 15 percentiles from established growth curve (on standard growth charts) which persists for 2 months or longer; or

b. An involuntary weight loss (or failure to gain weight at an appropriate rate for age) resulting in a fall to below the third percentile from established growth curve (on standard growth charts) which persists for 2 months or longer;

Or

G. Chronic hypoventilation ($PaCO_2$ greater than 45 mm Hg) or chronic cor pulmonale as described under the appropriate criteria in 104.02;

Or

H. Growth impairment as described under the criteria in 100.00.

103.03 Asthma. With:

A. FEV_1 equal to or less than the value specified in Table I or 103.02A:

Or

B. Attacks (as defined in 3.00C), in spite of prescribed treatment and requiring physician intervention, occurring at least once every 2 months or at least six times a year. Each inpatient hospitalization for longer than 24 hours for control of asthma counts as two attacks, and an evaluation period of at least 12 consecutive months must be used to determine the frequency of attacks.

Or

C. Persistent low-grade wheezing between acute attacks or absence of extended symptom-free periods requiring daytime and nocturnal use of sympathomimetic bronchodilators with one of the following:

1. Persistent prolonged expiration with radiographic or other appropriate imaging techniques evidence of pulmonary hyperinflation or peribronchial disease; or

2. Short courses of corticosteroids that average more than 5 days per month for at least 3 months during a 12-month period;

Or

D. Growth impairment as described under the criteria in 100.00.

103.04 *Cystic fibrosis.* With:

A. An FEV_1 equal to or less than the appropriate value specified in Table III corresponding to the child's height without shoes. (In cases of marked spinal deformity, see. 103.00B.);

Or

B. For children in whom pulmonary function testing cannot be performed, the presence of two of the following;

1. History of dyspnea on exertion or accumulation of secretions as manifested by repetitive coughing or cyanosis; or

2. Persistent bilateral rales and rhonchi or substantial reduction of breath sounds related to mucous plugging of the trachea or bronchi; or

3. Radiographic evidence of extensive disease, such as thickening of the proximal bronchial airways or persistence of bilateral peribronchial infiltrates;

Or

C. Persistent pulmonary infection accompanied by superimposed, recurrent, symptomatic episodes of increased bacterial infection occurring at least once every 6 months and requiring intravenous or nebulization antimicrobial treatment;

Or

D. Episodes of bronchitis or pneumonia or hemoptysis (more than blood-streaked sputum) or respiratory failure (documented according to 3.00C), requiring physician intervention, occurring at least once every 2 months or at least six times a year. Each inpatient hospitalization for longer than 24 hours for treatment counts as two episodes, and an evaluation period of at least 12 consecutive months must be used to determine the frequency of episodes;

Or

E. Growth impairment as described under the criteria in 100.00.

Table III
(Applicable only for evaluation under 103.04A – cystic fibrosis)

Height without shoes (centimeters)	Height without shoes (inches)	FEV_1 equal to or less than (L, BTPS)
119 or less	46 or less	0.75
120–129	47–50	0.85
130–139	51-54	1.05
140–149	55–58	1.35
150–159	T59–62	1.55
160–164	63–64	1.85
165–169T	65–66	2.05
170 or more	67 or more	2.25

104.00 Cardiovascular System

A. *Introduction.* The listings in this section describe childhood impairments resulting from congenital or acquired cardiovascular disease based on symptoms, physical signs, laboratory test abnormalities, and response to a regimen of therapy prescribed by a treating source. A longitudinal clinical record covering a period of not less than 3 months of observations and therapy is usually necessary for the assessment of severity and expected duration unless the child is a neonate or the claim can be decided favorably on the basis of the current evidence. All relevant evidence must be considered in assessing a child's disability. Reasonable efforts should be made to ensure evaluation by a program physician specializing in childhood cardiovascular impairments or a qualified pediatrician.

Examples of congenital defects include: abnormalities of cardiac septation, such as ventricular septal defect or atrioventricular (AV) canal; abnormalities resulting in cyanotic heart disease, such as tetralogy of Fallot or transposition of the vessels; valvular defects or obstructions to ventricular outflow, including

pulmonary or aortic stenosis and/or coarctation of the aorta; and major abnormalities of ventricular development, including hypoplastic left heart syndrome or pulmonary tricuspid atresia with hypoplastic right ventricle. Acquired heart disease may be due to cardiomyopathy, rheumatic heart disease, Kawasaki syndrome, or other etiologies. Recurrent arrhythmias, severe enough to cause functional impairment, may be seen with congenital or acquired heart disease or, more rarely, in children with structurally normal hearts.

Cardiovascular impairments, especially chronic heart failure and congenital heart disease, may result in impairments in other body systems including, but not limited to, growth, neurological, and mental. Therefore, evaluation should include consideration of the adverse effects of cardiovascular impairment in all relevant body systems, and especially on the child's growth and development, or mental functioning, as described under the Growth impairment (100.00), Neurological (111.00), and Mental retardation (112.05) listings.

Many children, especially those who have listing-level impairments, will have received the benefit of medically prescribed treatment. Whenever there is evidence of such treatment, the longitudinal clinical record must include a description of the therapy prescribed by the treating source and response, in addition to information about the nature and severity of the impairment. It is important to document any prescribed therapy and response because this medical management may have improved the child's functional status. The longitudinal record should provide information regarding functional recovery, if any.

Some children will not have received ongoing treatment or have an ongoing relationship with the medical community despite the existence of a severe impairment(s). Unless the claim can be decided favorably on the basis of the current evidence, a longitudinal record is still important because it will provide information about such things as the ongoing medical severity of the impairment, the level of the child's functioning, and the frequency, severity, and duration of symptoms. Also, several listings include a requirement for continuing signs and symptoms despite a regimen of prescribed treatment. Even though a child who does not receive treatment may not be able to show an impairment that meets the criteria of these listings, the child may have an impairment(s) equivalent in severity to one of the listed impairments or be disabled because of a substantial reduction in the ability to function independently, appropriately, and effectively in an age-appropriate manner.

Indeed, it must be remembered that these listings are only examples of common cardiovascular disorders that are severe enough to prevent a child from functioning independently, appropriately, and effectively in an age-appropriate manner. When a child has a medically determinable impairment that is not listed, or a combination of impairments no one of which meets a listing, we will make an equivalence determination. Also, with respect to children claiming SSI benefits under title XVI of the Act who have an impairment(s) with a level of severity which does not meet or equal the criteria of the cardiovascular listings, we will determine whether the impairment(s) is of comparable severity to one that would disable an adult. In these cases, an individualized functional assessment is crucial to the evaluation of a child's ability to function independently, appropriately, and effectively in an age-appropriate manner when

the impairment(s) is severe but the criteria of these listings are not met or equaled.

B. Documentation

Each child's file must include sufficiently detailed reports on history, physical examinations, laboratory studies, and any prescribed therapy and response to allow an independent reviewer to assess the severity and duration of the cardiovascular impairment. Data should be obtained preferably from an office or center experienced in pediatric cardiac assessment. The actual electrocardiographic tracing (or adequately marked photocopy) and echocardiogram report with a copy of relevant echocardiographic views should be included (see Part A, 4.00C1).

Results of additional studies necessary to substantiate the diagnosis or to document the severity of the impairment, including two-dimensional and Doppler echocardiography, and radionuclide ventriculograms, should be obtained as appropriate according to Part A, 4.00C3. Ambulatory electrocardiographic monitoring may also be obtained if necessary to document the presence or severity of an arrhythmia.

Exercise testing, though increasingly used, is still less frequently indicated in children than in adults, and can rarely be successfully performed in children under 6 years of age. It may be of value in the assessment of some arrhythmias, in the assessment of the severity of chronic heart failure, and in the assessment of recovery of function following cardiac surgery or other therapy. It will only be purchased by the Social Security Administration if the case cannot be decided based on the available evidence and, if purchased, must be performed in a specialty center for pediatric cardiology or other facility qualified to perform exercise testing for children.

Purchased exercise tests should be performed using a generally accepted protocol consistent with the prevailing state of medical knowledge and clinical practice. An exercise test should not be purchased for a child for whom the performance of the test is considered to constitute a significant risk by a program physician. See 4.00C2c.

Cardiac catheterization will not be purchased by the Social Security Administration. If the results of catheterization are otherwise available, they should be obtained.

C. Treatment and relationship to functional status.

In general, conclusions about the severity of a cardiovascular impairment cannot be made on the basis of type of treatment rendered or anticipated. The overall clinical and laboratory evidence, including the treatment plan(s) or results, should be persuasive that a listing-level impairment exists. The amount of function restored and the time required for improvement after treatment (medical, surgical, or a prescribed program of progressive physical activity) vary with the nature and extent of the disorder, the type of treatment, and other factors. Depending upon the timing of this treatment in relation to the alleged onset date of disability, impairment evaluation may need to be deferred for a period of up to 3 months from the date of treatment to permit consideration of

treatment effects. Evaluation should not be deferred if the claim can be favorably decided based upon the available evidence.

The most life-threatening forms of congenital heart disease and cardiac impairments, such as those listed in 104.00D, almost always require surgical treatment within the first year of life to prevent early death. Even with surgery, these impairments are so severe that it is likely that the impairment will continue to be disabling long enough to meet the duration requirement because of significant residual impairment post-surgery, or the recovery time from surgery, or a combination of both factors. Therefore, when the impairment is one of those named in 104.00D, or is as severe as one of those impairments, the presence of a listing-level impairment can usually be found on the basis of planned or actual cardiac surgery.

A child who has undergone surgical treatment for life-threatening heart disease will be found under a disability for 12 months following the date of surgery under 104.06H (for infants with life-threatening cardiac disease) or 104.09 (for a child of any age who undergoes cardiac transplantation) because of the uncertainty during that period concerning outcome or long-term results. After 12 months, continuing disability evaluation will be based upon residual impairment, which will consider the clinical course following treatment and comparison of symptoms, signs, and laboratory findings preoperatively and after the specified period.

D. Congenital heart disease.

Some congenital defects usually lead to listing-level impairment in the first year of life and require surgery within the first year as a life-saving measure. Examples of impairments that in most instances will require life-saving surgery before age 1, include, but are not limited to, the following: hypoplastic left heart syndrome; critical aortic stenosis with neonatal heart failure; critical coarctation of the aorta, with or without associated anomalies: complete AV canal defects; transposition of the great arteries; tetralogy of Fallot; and pulmonary atresia with intact ventricular septum.

In addition, there are rarer defects which may lead to early mortality and that may require multiple surgical interventions or a combination of surgery and other major interventional procedures (e.g., multiple “balloon” catheter procedures). Examples of such defects include single ventricle, tricuspid atresia, and multiple ventricular septal defects.

Pulmonary vascular obstructive disease can cause cardiac impairment in young children. When a large or nonrestrictive septal defect or ductus is present, pulmonary artery mean pressures of at least 70 percent of mean systemic levels are used as a criterion of listing-level impairment. In the absence of such a defect (i.e., with primary pulmonary hypertension, or in some connective tissue disorders with cardiopulmonary involvement and pulmonary vascular destruction), listing-level impairment may be present at lower levels of pulmonary artery pressure, in the range of at least 50 percent of mean systemic levels.

E. Chronic heart failure.

Chronic heart failure in infants and children may manifest itself by pulmonary or systemic venous congestion, including cardiomegaly, chronic dyspnea, tachypnea, orthopnea, or hepatomegaly; or symptoms of limited cardiac output, such as weakness or fatigue; or a need for cardiotonic drugs. Fatigue or exercise intolerance in an infant may be manifested by prolonged feeding time associated with signs of cardiac impairment, including excessive respiratory effort and sweating. Other manifestations of chronic heart failure during infancy may include failure to gain weight or involuntary loss of weight and repeated lower respiratory tract infections.

Cardiomegaly or ventricular dysfunction must be present and demonstrated by imaging techniques, such as two-dimensional and Doppler echocardiography. (Reference: Feigenbaum, Harvey, "Echocardiography," 4th Edition, Lea and Febiger, 1986, Appendix, pp. 621-639.) Chest x-ray (6 ft. PA film) will be considered indicative of cardiomegaly if the cardiothoracic ratio is over 60 percent at age 1 year or less, or 55 percent at more than 1 year of age.

Findings of cardiomegaly on chest x-ray must be accompanied by other evidence of chronic heart failure or ventricular dysfunction. This evidence may include clinical evidence, such as hepatomegaly, edema, or pulmonary venous congestion; or echocardiographic evidence, such as marked ventricular dilatation above established normals for age, or markedly reduced ejection fraction or shortening fraction.

F. Valvular heart disease.

Valvular heart disease requires documentation by appropriate imaging techniques, including Doppler echocardiogram studies or cardiac catheterization if catheterization results are available from a treating source or other source of record. Listing-level impairment is usually associated with critical aortic stenosis in a newborn child, persistent heart failure, arrhythmias, or valve replacement and ongoing anticoagulant therapy. The usual time after valvular surgery for adequate assessment of the results of treatment is considered to be 3 months.

G. Rheumatic heart disease.

The diagnosis should be made in accordance with the current revised Jones criteria for guidance in the diagnosis of rheumatic fever.

104.01 Category of Impairments, Cardiovascular System

104.02 *Chronic heart failure*. Documented by clinical and laboratory findings as described in 104.00E, and with one of the following:

A. Persistent tachycardia at rest (see Table I);

Or

B. Persistent tachypnea at rest (see Table II), or markedly decreased exercise tolerance (see 104.00E);

Or

C. Recurrent arrhythmias, as described in 104.05;

Or

D. Growth disturbance, with:

1. An involuntary weight loss (or failure to gain weight at an appropriate rate for age) resulting in a fall of 15 percentiles from established growth curve (on standard growth charts) which persists for 2 months or longer; or

2. An involuntary weight loss (or failure to gain weight at an appropriate rate for age) resulting in a fall to below the third percentile from established growth curve (on standard growth charts) which persists for 2 months or longer; or

3. Growth impairment as described under the criteria in 100.00.

Table I – Tachycardia at rest

Age	Apical Heart (Beats Per Minute)
Under 1 year	150
1 through 3 years	130
4 through 9 years	120
10 through 15 years	110
Over 15 years	100

Table II – Tachypnea at rest

Age	Respiratory (Rate Over Per Minute)
Under 1 year	40
1 through 5 years	35
6 through 9 years	30
Over 9 years	25

104.03 *Hypertensive cardiovascular disease.* With persistently elevated blood pressure equal to or greater than the 95th percentile for age (see Table III), and one of the following;

A. Impaired renal function, as described in 106.02;

Or

B. Cerebrovascular damage, as described in 111.06;

Or

C. Chronic heart failure as described in 104.02.

Table III – Elevated Blood Pressure

Age	Systolic Over (mmHg)	Or	Diastolic Over (mmHg)
Under 1 month	95		–
1 month through 2 years	112		74
3 through 5 years	116		76
6 through 9 years	122		78
10 through 12 years	126		82
13 through 15 years	136		86
16 to 18 years	142		92

104.05 *Recurrent arrhythmias*, such as persistent or recurrent heart block (A-V dissociation), repeated symptomatic tachyarrhythmias or bradyarrhythmias or long QT syndrome arrhythmias, not related to reversible causes such as electrolyte abnormalities or digitalis glycoside or antiarrhythmic drug toxicity, resulting in uncontrolled repeated episodes of cardiac syncope or near syncope and arrhythmia despite prescribed treatment, including electronic pacemaker (see 104.00A if there is no prescribed treatment), and documented by resting or ambulatory (Holter) electrocardiography coincident with the occurrence of syncope or near syncope.

104.06 *Congenital heart disease.* With one of the following:

A. Cyanotic heart disease, with persistent, chronic hypoxemia as manifested by;

1. Hematocrit of 55 percent or greater on two or more evaluations within a 3-month period; or

2. Arterial O_2 saturation of less than 90 percent in room air, or resting PO_2 of 60 Torr or less; or

3. Hypercyanotic spells, syncope, characteristic squatting, or other incapacitating symptoms directly related to documented cyanotic heart disease; or

4. Exercise intolerance with increased hypoxemia on exertion;

Or

B. Chronic heart failure with evidence of ventricular dysfunction, as described in 104.02;

Or

C. Recurrent arrhythmias as described in 104.05;

Or

D. Secondary pulmonary vascular obstructive disease with a mean pulmonary arterial pressure elevated to at least 70 percent of the mean systemic arterial pressure;

Or

E. Congenital valvular or other stenotic defects, or valvular regurgitation, as described in 104.00F and 104.07;

Or

F. Symptomatic acyanotic heart disease, with ventricular dysfunction resulting in significant restriction of age-appropriate activities or inability to complete age-appropriate tasks (see 104.00A);

Or

G. Growth failure, as described in 100.00;

Or

H. For infants under 12 months of age at the time of filing, with life-threatening congenital heart impairment that will or has required surgical treatment in the first year of life, consider the infant to be under a disability until the attainment of age 1 or for 12 months after surgery, whichever is the later event; thereafter, evaluate impairment severity with reference to 104.02 to 104.08.

104.07 *Valvular heart disease or other stenotic defects, or valvular regurgitation,* documented by appropriate imaging techniques or cardiac catheterization.

A. Evaluate according to criteria in 104.02, 104.05, 111.06, or 11.04:

Or

B. Critical aortic stenosis in newborn.

104.08 *Cardiomyopathies,* documented by appropriate imaging techniques, including echocardiography or cardiac catheterization, if catheterization results are available from a treating source. Impairment must be associated with an ejection fraction of 50 percent or less and significant left ventricular dilatation using standardized age-appropriate echocardiographic ventricular cavity measurements. Evaluate under the criteria in 104.02, 104.05, or 111.06.

104.09 *Cardiac transplantation.* Consider under a disability for 1 year following surgery; thereafter, evaluate residual impairment under 104.02 to 104.08.

104.13 *Chronic rheumatic fever or rheumatic heart disease*. Consider under a disability for 18 months from the established onset of impairment with one of the following:

A. Persistence of rheumatic fever activity for 6 months or more which is manifested by significant murmur(s), cardiac enlargement (see 104.00E) or ventricular dysfunction, and other abnormal laboratory findings, as for example, an elevated sedimentation rate or ECG findings:

Or

B. Evidence of chronic heart failure, as described under 104.02;

Or

C. Recurrent arrhythmias, as described under 104.05.

104.14 *Hyperlipidemia.* Documented Type II homozygous hyperlipidemia with repeated plasma cholesterol levels of 500 mg/ml or greater, with one of the following:

A. Myocardial ischemia, as described in 4.04B or 4.04C;

Or

B. Significant aortic stenosis documented by Doppler echocardiographic techniques or cardiac catheterization;

Or

C. Major disruption of normal life activities by repeated hospitalizations for plasmapheresis or other prescribed therapies, including liver transplant;

Or

D. Recurrent pancreatitis complicating hyperlipidemia.

104.15 *Kawasaki syndrome.* With one of the following:

A. Major coronary artery aneurysm;

Or

B. Chronic heart failure, as described in 104.02.

105.00 Digestive System

A. *Disorders of the digestive system* which result in disability usually do so because of interference with nutrition and growth, multiple recurrent inflammatory lesions, or other complications of the disease. Such lesions or complications usually respond to treatment. To constitute a listed impairment, these must be shown to have persisted or be expected to persist despite prescribed therapy for a continuous period of at least 12 months.

B. *Documentation of gastrointestinal impairments* should include pertinent operative findings, radiographic studies, endoscopy, and biopsy reports. Where a liver biopsy has been performed in chronic liver disease, documentation should include the report of the biopsy.

C. *Growth retardation and malnutrition.* When the primary disorder of the digestive tract has been documented, evaluate resultant malnutrition under the criteria described in 105.08. Evaluate resultant growth impairment under the criteria described in 100.03. Intestinal disorders, including surgical diversions

and potentially correctable congenital lesions, do not represent a severe impairment if the individual is able to maintain adequate nutrition, growth, and development.

D. *Multiple congenital anomalies.* See related criteria, and consider as a combination of impairments.

105.01 Category of Impairments Digestive

105.03 *Esophageal Obstruction, caused by atresia, stricture, or stenosis,* with malnutrition as described under the criteria in 105.08.

105.05 *Chronic Liver Disease.* With one of the following:

A. Inoperable biliary atresia demonstrated by X-ray or surgery; or

B. Intractable ascites not attributable to other causes, with serum albumin of 3.0 gm./100 ml. or less; or

C. Esophageal varices (demonstrated by angiography, barium swallow, or endoscopy or by prior performance of a specific shunt or plication procedure); or

D. Hepatic coma, documented by findings from hospital records; or

E. Hepatic encephalopathy. Evaluate under the criteria in 112.02; or

F. Chronic active inflammation or necrosis documented by SGOT persistently more than 100 units or serum bilirubin of 2.5 mg. percent or greater.

105.07 *Chronic inflammatory bowel disease* (such as ulcerative colitis, regional enteritis), as documented in 105.00. With one of the following:

A. Intestinal manifestations or complications, such as obstruction, abscess, or fistula formation which has lasted or is expected to last 12 months; or

B. Malnutrition as described under the criteria in 105.08; or

C. Growth impairment as described under the criteria in 100.03.

105.08 *Malnutrition,* due to demonstrable gastrointestinal disease causing either a fall of 15 percentiles of weight which persists or the persistence of weight which is less than the third percentile (on standard growth charts). And one of the following:

A. Stool fat excretion per 24 hours:

1. More than 15 percent in infants less than 6 months.

2. More than 10 percent in infants 6-18 months.

3. More than 6 percent in children more than 18 months; or

B. Persistent hematocrit of 30 percent or less despite prescribed therapy; or

C. Serum carotene of 40 mcg./100 ml. or less; or

D. Serum albumin of 3.0 gm./100 ml. or less.

106.00 Genito-Urinary System

A. *Determination of the presence of chronic renal disease* will be based upon the following factors:

1. History, physical examination, and laboratory evidence of renal disease.

2. Indications of its progressive nature or laboratory evidence of deterioration of renal function.

B. *Renal transplant.* The amount of function restored and the time required to effect improvement depend upon various factors including adequacy of post transplant renal function, incidence of renal infection, occurrence of rejection crisis, presence of systemic complications (anemia, neuropathy, etc.) and side effects of corticosteriod or immuno-suppressive agents. A period of at least 12 months is required for the individual to reach a point of stable medical improvement.

C. Evaluate associated disorders and complications according to the appropriate body system listing.

106.01 Category of Impairments, Genito-Urinary

106.02 *Chronic Renal Disease.* With:

A. Persistent elevation of serum creatinine to 3 mg. per deciliter (100 ml.) or greater, over at least 3 months; or

B. Reduction of creatinine clearance to 30 ml. per minute (43 liters/24 hours) per 1.73m^2 of body surface area over at least 3 months, or

C. Chronic renal dialysis program for irreversible renal failure; or

D. Renal transplant. Consider under a disability for 12 months following surgery; thereafter evaluate the residual impairment (see 106.00B).

106.06 *Nephrotic Syndrome,* with edema not controlled by prescribed therapy. And:

A. Serum albumin less than 2 gm./100 ml.; or

B. Proteinuria more than 2.5 gm./1.73 m^2/day.

107.00 Hemic and Lymphatic System

A. *Sickle cell disease.* Refers to a chronic hemolytic anemia associated with sickle cell hemoglobin, either homozygous or in combination with thalassemia or with another abnormal hemoglobin (such as C or F).

Appropriate hematologic evidence for sickle cell disease, such as hemoglobin electrophoresis must be included. Vaso-occlusive, hemolytic, or aplastic

episodes should be documented by description of severity, frequency,and duration.

Disability due to sickle cell disease may be solely the result of a severe, persistent anemia or may be due to the combination of chronic progressive or episodic manifestations in the presence of a less severe anemia.

Major visceral episodes causing disability include meningitis, osteomyelitis, pulmonary infections or infarctions, cerebrovascular accidents, congestive heart failure, genito-urinary involvement, etc.

B. *Coagulation defects.*Chronic inherited coagulation disorders must be documented by appropriate laboratory evidence such as abnormal thromboplastin generation, coagulation time, or factor assay.

C. *Acute leukemia.*Initial diagnosis of acute leukemia must be based upon definitive bone marrow pathologic evidence. Recurrent disease may be documented by peripheral blood, bone marrow, or cerebrospinal fluid examination. The pathology report must be included.

The designated duration of disability implicit in the finding of a listed impairment is contained in 107.11. Following the designated time period, a documented diagnosis itself is no longer sufficient to establish a severe impairment. The severity of any remaining impairment must be evaluated on the basis of the medical evidence.

107.01 Category of Impairments, Hematic and Lymphatic

107.03 *Hemolytic Anemia* (due to any cause). Manifested by persistence of hematocrit of 26 percent or less despite prescribed therapy, and reticulocyte count of 4 percent or greater.

107.05 *Sickle cell disease*. With:

A. Recent, recurrent severe vaso-occlusive crises (musculoskeletal, vertebral, abdominal); or

B. A major visceral complication in the 12 months prior to application; or

C. A hyperhemolytic or aplastic crisis within 12 months prior to application; or

D. Chronic, severe anemia with persistence of hematocrit of 26 percent or less; or

E. Congestive heart failure, cerebrovascular damage, or emotional disorder as described under the criteria in 104.02, 111.00ff, or 112.00ff.

107.06 *Chronic idiopathic thrombocytopenic purpura of childhood.* With purpura and thrombocytopenia of 40,000 platelets/cu.mm. or less despite prescribed therapy or recurrent upon withdrawal of treatment.

107.08 *Inherited coagulation disorder* . With:

A. Repeated spontaneous or inappropriate bleeding; or

B. Hemarthrosis with joint deformity.

107.11 *Acute leukemia.* Consider under a disability:

A. For 2 1/2 years from the time of initial diagnosis; or

B. For 2 1/2 years from the time of recurrence of active disease.

109.00 Endocrine System

A. *Cause of disability.* Disability is caused by a disturbance in the regulation of the secretion or metabolism of one or more hormones which are not adequately controlled by therapy. Such disturbances or abnormalities usually respond to treatment. To constitute a listed impairment these must be shown to have persisted or be expected to persist despite prescribed therapy for a continuous period of at least 12 months.

B. *Growth.* Normal growth is usually a sensitive indicator of health as well as of adequate therapy in children. Impairment of growth may be disabling in itself or may be an indicator of a severe disorder involving the endocrine system or other body systems. Where involvement of other organ systems has occurred as a result of a primary endocrine disorder, these impairments should be evaluated according to the criteria under the appropriate sections.

C. *Documentation.* Description of characteristic history, physical findings, and diagnostic laboratory data must be included. Results of laboratory tests will be considered abnormal if outside the normal range or greater than two standard deviations from the mean of the testing laboratory. Reports in the file should contain the information provided by the testing laboratory as to their normal values for that test.

D. *Hyperfunction of the adrenal cortex.* Evidence of growth retardation must be documented as described in 100.00. Elevated blood or urinary free cortisol levels are not acceptable in lieu of urinary 17-hydroxycorticosteroid excretion for the diagnosis of adrenal cortical hyperfunction.

E. *Adrenal cortical insufficiency.* Documentation must include persistent low plasma cortisol or low urinary 17-hydroxycorticosteroids or 17-ketogenic steroids and evidence of unresponsiveness to ACTH stimulation.

109.01 Category of impairments, Endocrine

109.02 *Thyroid Disorders.*

A. *Hyperthyroidism (as documented in 109.00C above).* With clinical manifestations despite prescribed therapy, and one of the following:

1. Elevated serum thyroxine (T_4) and either elevated free T_4 or resin T_3 uptake; or

2. Elevated thyroid uptake of radioiodine; or

3. Elevated serum triiodothyronine (T_3).

B. *Hypothyroidism.*With one of the following, despite prescribed therapy:

1. IQ of 70 or less; or

2. Growth impairment as described under the criteria in 100.02A and B; or

3. Precocious puberty.

109.03 *Hyperparathyroidism (as documented in 109.00C).* With:

A. Repeated elevated total or ionized serum calcium; or

B. Elevated serum parathyroid hormone.

109.04 *Hypoparathyroidism or Pseudohypoparathyroidism.* With:

A. Severe recurrent tetany or convulsions which are unresponsive to prescribed therapy; or

B. Growth retardation as described under the criteria in 100.02A and B.

109.05 *Diabetes insipidus*,documented by pathologic hypertonic saline or water deprivation test. And one of the following:

A. Intracranial space-occupying lesion, before or after surgery; or

B. Unresponsiveness to Pitressin; or

C. Growth retardation as described under the criteria in 100.02A and B; or

D. Unresponsive hypothalmic thirst center, with chronic or recurrent hypernatremia; or

E. Decreased visual fields attributable to a pituitary lesion.

109.06 *Hyperfunction of the Adrenal Cortex (Primary or Secondary).* With:

A. Elevated urinary 17-hydroxycorticosteroids (or 17-ketogenic steroids) as documented in 109.00C and D; and

B. Unresponsiveness to low-dose dexamethasone suppression.

109.07 *Adrenal cortical insufficiency, (As documented in 109.00C and E)* with recent, recurrent episodes of circulatory collapse.

109.08 *Juvenile Diabetes Mellitus (as documented in 109.00C) requiring parenteral insulin.* And one of the following, despite prescribed therapy:

A. Recent, recurrent hospitalizations with acidosis; or

B. Recent, recurrent episodes of hypoglycemia; or

C. Growth retardation as described under the criteria in 100.02.A or B; or

D. Impaired renal function as described under the criteria in 106.00ff.

109.09 *Iatrogenic hypercorticoid state.* With chronic glucocorticoid therapy resulting in one of the following:

A. Osteoporosis; or

B. Growth retardation as described under the criteria in 100.02A or B; or

C. Diabetes mellitus as described under the criteria in 109.08; or

D. Myopathy as described under the criteria in 111.06; or

E. Emotional disorder as described under the criteria in 112.00ff.

109.10 *Pituitary Dwarfism (With documented growth hormone deficiency).* And growth impairment as described under the criteria in 100.02B.

109.11 *Adrenogenital Syndrome.* With:

A. Recent, recurrent salt-losing episodes despite prescribed therapy; or

B. Inadequate replacement therapy manifested by accelerated bone age and virilization; or

C. Growth impairment as described under the criteria in 100.02A or B.

109.12 *Hypoglycemia* (as documented in 109.00C). With recent, recurrent hypoglycemic episodes producing convulsion or coma.

109.13 *Gonadal Dysgenesis (Turner's Syndrome), chromosomally proven.* Evaluate the resulting impairment under the criteria for the appropriate body system.

110.00 Multiple Body Systems

A. This section refers to those life-threatening catastrophic congenital abnormalities and other serious hereditary, congenital, or acquired disorders that usually affect two or more body systems and are expected to:

1. Result in early death or developmental attainment of less than 2 years of age as described in listing 110.08 (e.g., anencephaly or Tay-Sachs); or

2. Produce long-term, if not life-long, significant interference with age-appropriate major daily or personal care activities as described in listings 110.06 and 110.07. (Significant interference with age-appropriate activities is considered to exist where the developmental milestone age did not exceed two-thirds of the chronological age at the time of evaluation and such interference has lasted or could be expected to last at least 12 months.) See 112.00C for a discussion of developmental milestone criteria and evaluation of age-appropriate activities.

Down syndrome (except for mosaic Down syndrome, which is to be evaluated under listing 110.07) established by clinical findings, including the characteristic physical features, and laboratory evidence is considered to meet the requirement of listing 110.06 commencing at birth. Examples of disorders that should be

evaluated under listing 110.07 include mosaic Down Syndrome and chromosomal abnormalities other than Down syndrome, in which a pattern of multiple impairments (including mental retardation) is known to occur, phenylketonuria (PKU), fetal alcohol syndrome, and severe chronic neonatal infections such as toxoplasmosis, rubella syndrome, cytomegalic inclusion disease, and herpes encephalitis.

B. Documentation must include confirmation of a positive diagnosis by a clinical description of the usual abnormal physical findings associated with the condition and definitive laboratory tests, including chromosomal analysis, where appropriate (e,g,. Down Syndrome). Medical evidence that is persuasive that a positive diagnosis has been confirmed by appropriate laboratory testing, at some time prior to evaluation, is acceptable in lieu of a copy of the actual laboratory report.

C. When multiple body system manifestations do not meet one of the established criteria of one of the listings, the combined impairments must be evaluated together to determine if they are equal in severity to a listed impairment.

110.01 Category of Impairments, Multiple Body Systems

110.06 *Down Syndrome* (excluding mosaic Down syndrome) established by clinical and laboratory findings, as described in 110.00B. Consider the child disabled from birth.

110.07 *Multiple body dysfunction* due to any confirmed (see 110.00B) hereditary, congenital, or acquired condition with one of the following:

A. Persistent motor dysfunction as a result of hypotonia and/or musculoskeletal weakness, postural reaction deficit, abnormal primitive reflexes, or other neurological impairment as described in 111.00C, and with significant interference with age-appropriate major daily or personal care activities, which in an infant or young child include such activities as head control, swallowing, following, reaching, grasping, turning, sitting, crawling, walking, taking solids, feeding self; or

B. Mental impairment as described under the criteria in 112.05 or 112.12; or

C. Growth impairment as described under the criteria in 100.02A or B; or

D. Significant interference with communication due to speech, hearing, or visual impairments as described under the criteria in 102.00 and 111.09; or

E. Cardiovascular impairments as described under the criteria in 104.00; or

F. Other impairments such as, but not limited to malnutrition, hypothyroidism, or seizures should be evaluated under the criteria in 105.08, 109.02 or 111.02 and 111.03, or the criteria for the affected body system.

110.08 *Catastrophic Congenital Abnormalities or Disease.* With

A. A positive diagnosis (such as anencephaly, trisomy D or E, cyclopia, etc.), generally regarded as being incompatible with extrauterine life; or

B. A positive diagnosis (such as cri du chat, Tay-Sachs Disease) wherein attainment of the growth and development level of 2 years is not expected to occur.

111.00 Neurological.

A. *Seizure disorder* must be substantiated by at least one detailed description of a typical seizure. Report of recent documentation should include an electroencephalogram and neurological examination. Sleep EEG is preferable, especially with temporal lobe seizures. Frequency of attacks and any associated phenomena should also be substantiated.

Young children may have convulsions in association with febrile illnesses. Proper use of 111.02 and 111.03 requires that a seizure disorder be established. Although this does not exclude consideration of seizures occurring during febrile illnesses, it does require documentation of seizures during nonfebrile periods.

There is an expected delay in control of seizures when treatment is started, particularly when changes in the treatment regimen are necessary. Therefore, a seizure disorder should not be considered to meet the requirements of 111.02 or 111.03 unless it is shown that seizures have persisted more than three months after prescribed therapy began.

B. *Minor motor seizures.* Classical petit mal seizures must be documented by characteristic EEG pattern, plus information as to age at onset and frequency of clinical seizures. Myoclonic seizures, whether of the typical infantile or Lennox-gastaut variety after infancy, must also be documented by the characteristic EEG pattern plus information as to age at onset and frequency of seizures.

C. *Motor dysfunction.* As described in 111.06, motor dysfunction may be due to any neurological disorder. It may be due to static or progressive conditions involving any area of the nervous system and producing any type of neurological impairment. This may include weakness, spasticity, lack of coordination, ataxia, tremor, athetosis, or sensory loss. Documentation of motor dysfunction must include neurologic findings and description of type of neurologic abnormality (e.g., spasticity, weakness), as well as a description of the child's functional impairment (i.e., what the child is unable to do because of the abnormality). Where a diagnosis has been made, evidence should be included for substantiation of the diagnosis (e.g., blood chemistries and muscle biopsy reports), wherever applicable.

D. *Impairment of communication.* The documentation should include a description of a recent comprehensive evaluation, including all areas of affective and effective communication, performed by a qualified professional.

111.01 Category of Impairment Neurological

111.02 *Major motor seizure disorder*

A. *Major Motor seizures.* In a child with an established seizure disorder, the occurrence of more than one major motor seizure per month despite at least three months of prescribed treatment. With:

1. Daytime episodes (loss of consciousness and convulsive seizures); or

2. Nocturnal episodes manifesting residuals which interfere with activity during the day.

B. *Major motor seizures.* In a child with an established seizure disorder, the occurrence of at least one major motor seizure in the year prior to application despite at least three months of prescribed treatment. and one of the following:

1. IQ of 70 or less; or

2. Significant interference with communication due to speech, hearing, or visual defect; or

3. Significant emotional disorder; or

4. Where significant adverse effects of medication interfere with major daily activities.

111.03 *Minor motor seizure disorder.* In a child with an established seizure disorder, the occurrence of more than one minor motor seizure per week, with alteration of awareness or loss of consciousness, despite at least three months of prescribed treatment.

111.05 *Brain tumors*

A. Malignant gliomas (astrocytoma - Grades III and IV, glioblastoma multiforme), medulloblastoma, ependymoblastoma, primary sarcoma, or brain stem gliomas; or

B. Evaluate other brain tumors under the criteria for the resulting neurological impairment.

111.06 *Motor dysfunction (Due to any neurological disorder.)* Persistent disorganization or deficit of motor function for age involving two extremities, which (despite prescribed therapy) interferes with age-appropriate major daily activities and results in disruption of:

A. Fine and gross movements; or

B. Gait and station.

111.07 *Cerebral palsy* with:

A. Motor dysfunction meeting the requirements of 101.03 or 111.06; or

B. Less severe motor dysfunction (but more than slight) and one of the following:

1. IQ of 70 or less; or

2. Seizure disorder, with at least one major motor seizure in the year prior to application; or

3. Significant interference with communication due to speech, hearing, or visual defect; or

4. Significant emotional disorder.

111.08 *Meningomyelocele (and related disorders).* With one of the following despite prescribed treatment:

A. Motor dysfunction meeting the requirements of 101.03 or 111.06; or

B. Less severe motor dysfunction (but more than slight), and:

1. Urinary or fecal incontinence when inappropriate for age; or

2. IQ of 70 or less; or

C. Four extremity involvement; or

D. Noncompensated hydrocephalus producing interference with mental or motor developmental progression.

111.09 *Communication impairment, associated with documented neurological disorder.* And one of the following:

A. Documented speech deficit which significantly affects the clarity and content of the speech; or

B. Documented comprehension deficit resulting in ineffective verbal communication for age; or

C. Impairment of hearing as described under the criteria in 102.08.

112.00 Mental Disorders

A. *Introduction:* The structure of the mental disorders listings for children under age 18 parallels the structure for the mental disorders listings for adults but is modified to reflect the presentation of mental disorders in children. The listings for mental disorders in children are arranged in 11 diagnostic categories: Organic mental disorders (112.02); schizophrenic, delusional (paranoid), schizoaffective, and other psychotic disorders (112.03); mood disorders (112.04); mental retardation (112.05); anxiety disorders (112.06); somatoform, eating, and tic disorders (112.07); personality disorders (112.08); psychoactive substance dependence disorders (112.09); autistic disorder and other pervasive developmental disorders (112.10); attention deficit hyperactivity disorder (112.11); and developmental and emotional disorders of newborn and younger infants (112.12).

There are significant differences between the listings for adults and the listings for children. There are disorders found in children that have no real analogy in adults; hence, the differences in the diagnostic categories for children. The presentation of mental disorders in children, particularly the very young child, may be subtle and of a character different from the signs and symptoms found in adults. For example, findings such as separation anxiety, failure to mold or bond with the parents, or withdrawal may serve as findings comparable to findings that mark mental disorders in adults. The activities appropriate to children, such as learning, growing, playing, maturing, and school adjustment, are also different from the activities appropriate to the adult and vary widely in the different childhood stages.

Each listing begins with an introductory statement that describes the disorder or disorders addressed by the listing. This is followed (except in listings 112.05 and 112.12) by medical findings (paragraph A criteria), which, if satisfied, lead to an assessment of impairment-related functional limitations (paragraph B criteria). An individual will be found to have a listed impairment when the criteria of both paragraphs A and B of the listed impairment are satisfied.

The purpose of the criteria in paragraph A is to substantiate medically the presence of a particular mental disorder. Specific symptoms and signs under any of the listings 112.02 through 112.12 cannot be considered in isolation from the description of the mental disorder contained at the beginning of each listing category. Impairments should be analyzed or reviewed under the mental category(ies) indicated by the medical findings.

Paragraph A of the listings is a composite of medical findings which are used to substantiate the existence of a disorder and may or may not be appropriate for children at specific developmental stages. However, a range of medical findings is included in the listings so that no age group is excluded. For example, in listing 112.02A7, emotional lability and crying would be inappropriate criteria to apply to older infants and toddlers, age 1 to attainment of age 3; whereas in 112.02A1, developmental arrest, delay, or regression are appropriate criteria for older infants and toddlers. Whenever the adjudicator decides that the requirements of paragraph A of a particular mental listing are satisfied, then that listing should be applied regardless of age of the child to be evaluated.

The purpose of the paragraph B criteria is to describe impairment-related functional limitations which are applicable to children. Standardized tests of social or cognitive function and adaptive behavior are frequently available and appropriate for the evaluation of children and, thus, such tests are included in the paragraph B functional parameters. The functional restrictions in paragraph B must be the result of the mental disorder which is manifested by the medical findings in paragraph A.

We have not included separate C criteria for listing 112.03 and 112.06, as are found in the adult listings, because for the most part we do not believe that categories like residual schizophrenia of agoraphobia are commonly found in children. However, in unusual cases where these disorders are found in children and are comparable to the severity and duration found in adults, the adult 12.03C and 12.06C criteria may be used for evaluation of the cases.

The structure of the listings for Mental Retardation (112.05) and Developmental and Emotional Disorders of Newborn and Younger infants (112.12) is different from that of the other mental disorders. Listing 112.05 (Mental Retardation) contains six sets of criteria, any one of which, if satisfied, will result in a finding that the child's impairment meets the listing. Listing 112.12 (Developmental and Emotional Disorders of Newborn and Younger Infants) contains five criteria, any one of which, if satisfied, will result in a finding that the infant's impairment meets the listing.

It must be remembered that these listings are examples of common mental disorders which are severe enough to find a child disabled. When a child has a medically determinable impairment that is not listed or a combination of impairments no one of which meets a listing, we will make a medical equivalency determination. This determination can be especially important in older infants and toddlers (age 1 to attainment of age 3), who may be too young for identification of a specific diagnosis, yet demonstrate serious functional limitations. Therefore, the determination of equivalency is necessary to the evaluation of any child's case when the child does not have an impairment that meets a listing.

B. *Need for Medical Evidence:* The existence of a medically determinable impairment of the required duration must be established by medical evidence consisting of symptoms, signs, and laboratory findings (including psychological or developmental test findings). Symptoms are complaints presented by the child. Psychiatric signs are medically demonstrable phenomena which indicate specific abnormalities of behavior, affect, thought, memory, orientation, development, and contact with reality, as described by an appropriate medical source. Symptoms and signs generally cluster together to constitute recognizable mental disorders described in paragraph A of the listings. These findings may be intermittent or continuous depending on the nature of the disorder.

C. *Assessment of Severity:* In childhood cases, as with adults, severity is measured according to the functional limitations imposed by the medically determinable mental impairment. However, the range of functions used to assess impairment severity for children varies at different stages of maturation. The functional areas that we consider are: Motor function; cognitive/communicative function; social function; personal/behavioral function; and concentration, persistence, and pace. In most functional areas, there are two alternative methods of documenting the required level of severity; (1) use of standardized tests alone, where appropriate test instruments are available, and (2) use of other medical findings. (See 112.00D for an explanation of these documentation requirements.) The use of standardized tests is the preferred method of documentation if such tests are available.

Newborn and younger infants (birth to attainment of age 1) have not developed sufficient personality differentiation to permit formulation of appropriate diagnoses. We have, therefore, assigned listing 112.12 for Developmental and Emotional Disorders of Newborn and Younger Infants for the evaluation of mental disorders of such children. Severity of these disorders is based on measures of development in motor, cognitive/communicative, and social functions. When older infants and toddlers (age 1 to attainment of age 3) do not

clearly satisfy the paragraph A criteria of any listing because of insufficient developmental differentiation, they must be evaluated under the rules for equivalency. The principles for assessing the severity of impairment in such children, described in the following paragraphs, must be employed.

In defining the severity of functional limitations, two different sets of paragraph B criteria corresponding to two separate age groupings have been established, in addition to listing 112.12, which is for children who have not attained age 1. These age groups are: older infants and toddlers (age 1 to attainment of age 3) and children (age 3 to attainment of age 18). However, the discussion below in 112.00C1, 2 , 3, and 4, on the age appropriate areas of function, is broken down into four age groupings: older infants and toddlers (age 1 to attainment of age 3), preschool children (age 3 to attainment of age 6), primary school children (age 6 to attainment of age 12), and adolescents (age 12 to attainment of age 18). This was done to provide specific guidance on the age group variances in disease manifestations and methods of evaluation.

Where "marked" is used as a standard for measuring the degree of limitation it means more than moderate but less than extreme. A marked limitation may arise when several activities or functions are impaired, or even when only one is impaired, as long as the degree of limitation is such as to interfere seriously with the ability to function (based upon age-appropriate expectations) independently, appropriately, effectively, and on a sustained basis. When standardized tests are used as the measure of functional parameters, a valid score that is two standard deviations below the norm for the test will be considered a marked restriction.

1. *Older infants and toddlers (age 1 to attainment of age 3).* In this age group, impairment severity is assessed in three areas: (a) Motor development, (b) cognitive/communicative function, and (c) social function.

a. *Motor development.* Much of what we can discern about mental function in these children frequently comes from observation of the degree of development of fine and gross motor function. Developmental delay, as measured by a good developmental milestone history confirmed by medical examination, is critical. This information will ordinarily be available in the existing medical evidence from the claimant's treating sources and other medical sources, supplemented by information from nonmedical sources, such as parents, who have observed the child and can provide pertinent historical information. It may also be available from standardized testing. If the delay is such that the older infant or toddler has not achieved motor development generally acquired by children no more than one-half the child's chronological age, the criteria are satisfied.

b. *Cognitive/communicative function.* Cognitive/communicative function is measured using one of several standardized infant scales. Appropriate tests for the measure of such function are discussed in 112.00D. Care should be taken to avoid reliance on screening devices, which are not generally considered to be sufficiently reliable instruments, although such devices may provide some relevant data; however, there will be cases in which the results of such tests show such severe abnormalities that further testing will be unnecessary.

For older infants and toddlers, alternative criteria covering disruption in communication as measured by their capacity to use simple verbal and nonverbal structures to communicate basic needs are provided.

c. *Social function.* Social function in older infants and toddlers is measured in terms of the development of relatedness to people (e.g., bonding and stranger anxiety) and attachment to animate or inanimate objects. Criteria are provided that use standard social maturity scales or alternative criteria that describe marked impairment in socialization.

2. *Preschool children (age 3 to attainment of age 6).* For the age groups including preschool children through adolescence, the functional areas used to measure severity are: (a) Cognitive/communicative function, (b) social function, (c) personal/behavioral function, and (d) deficiencies of concentration, persistence, or pace resulting in frequent failure to complete tasks in a timely manner. After 36 months, motor function is no longer felt to be a primary determinant of mental function, although, of course, any motor abnormalities should be documented and evaluated.

a. *Cognitive/communicative function.* In the preschool years and beyond, cognitive function can be measured by standardized tests of intelligence, although the appropriate instrument may vary with age. A primary criterion for limited cognitive function is a valid verbal, performance, or full scale IQ of 70 or less. The listings also provide alternative criteria, consisting of tests of language development or bizarre speech patterns.

b. *Social function.* Social function is measured by an assessment of a child's relationships with parents, other adults, and peers. These relationships are often observed not only at home but also in preschool programs, where the child's interactions with other children and teachers come under daily scrutiny.

c. *Personal/behavioral function.* This function may be measured by a standardized test of adaptive behavior or by careful description of maladaptive or avoidant behaviors. These behaviors are often observed not only at home but also in preschool programs.

d. *Concentration, persistence, and pace.* This function may be measured through observations of the child in the course of standardized testing and in the course of play.

3. *Primary school children (age 6 to attainment of age 12).* The measures of function here are similar to those for preschool-age children except that the test instruments may change and the capacity to function in the school setting is supplemental information. Standardized measures of academic achievement, e.g., Wide Range Achievement Test-Revised, Peabody Individual Achievement Test, etc., may be helpful in assessing cognitive impairment. Problems in social functioning, especially in the area of peer relationships, are often observed firsthand by teachers and school nurses. As described in 112.00D, *Documentation*, school records are an excellent source of information concerning function and standardized testing and should always be sought for school-age children.

As it applies to primary school children, the intent of the functional criterion described in paragraph B2d, i.e., deficiencies of concentration, persistence, or pace resulting in failure to complete tasks in a timely manner, is to identify the child who cannot adequately function in primary school because of a mental impairment. Although grades and the need for special education placement are

relevant factors which must be considered in reaching a decision under paragraph B2d, they are not conclusive. There is too much variability from school district to school district in the expected level of grading and in the criteria for special education placement to justify reliance solely on these factors.

4. *Adolescents (age 12 to attainment of age 18).* Functional criteria parallel to those for primary school children (cognitive/communicative; social; personal/behavioral; and concentration, persistence, and pace) are the measure of severity for this age group. Testing instruments appropriate to adolescents should be used where indicated. Comparable findings of disruption of social function must consider the capacity to form appropriate, stable, and lasting relationships. If information is available about cooperative working relationships in school or at part-time or full-time work, or about the ability to work as a member of a group, it should be considered when assessing the child's social and personal/behavioral functioning. Markedly impoverished social contact, isolation, withdrawal, and inappropriate or bizarre behavior under the stress of socializing with others also constitute comparable findings.

In adolescents, the intent of the functional criterion described in paragraph B2d is the same as in primary school children. However, other evidence of this functional impairment may also be available, such as from evidence of the child's performance in work or work-like settings.

D. *Documentation:*The presence of a mental disorder in a child must be documented on the basis of reports from acceptable sources of medical evidence. Descriptions of functional limitations may be available from these sources, either in the form of standardized test results or in other medical findings supplied by the sources, or both. (Medical findings consist of symptoms, signs, and laboratory findings.) Whenever possible, a medical source's findings should reflect the medical source's consideration of information from parents or other concerned individuals who are aware of the child's activities of daily living, social functioning, and ability to adapt to different settings and expectations, as well as the medical source's findings and observations on examination, consistent with standard clinical practice. As necessary, information from nonmedical sources, such as parents, should also be used to supplement the record of the child's functioning to establish the consistency of the medical evidence and longitudinality of impairment severity.

For some newborn and younger infants, it may be very difficult to document the presence of severity of a mental disorder. Therefore, with the exception of some genetic diseases and catastrophic congenital anomalies, it may be necessary to defer making a disability decision until the child attains 3 months of age in order to obtain adequate observation of behavior or affect. See, also, 110.00 of this part. This period could be extended in cases of premature infants depending on the degree of prematurity and the adequacy of documentation of their developmental and emotional status.

For infants and toddlers, programs of early intervention involving occupational, physical, and speech therapists, nurses, social workers, and special educators, are a rich source of data. They can provide the developmental milestone evaluations and records on the fine and gross motor functioning of these children. This information is valuable and can complement the medical examination by a physician or psychologist. A report of an interdisciplinary

team that contains the evaluation and signature of an acceptable medical source is considered acceptable medical evidence rather than supplemental data.

In children with mental disorders, particularly those requiring special placement, school records are a rich source of data, and the required reevaluations at specified time periods can provide the longitudinal data needed to trace impairment progression over time.

In some cases where the treating sources lack expertise in dealing with mental disorders of children, it may be necessary to obtain evidence from a psychiatrist, psychologist, or pediatrician with experience and skill in the diagnosis and treatment of mental disorders as they appear in children. In these cases, however, every reasonable effort must be made to obtain the records of the treating sources, since these records will help establish a longitudinal picture that cannot be established through a single purchased examination.

A reference to standardized psychological testing indicates the use of a psychological test that has appropriate characteristics of validity, reliability, and norms, administered individually by a psychologist, psychiatrist, pediatrician, or other physician specialist qualified by training and experience to perform such an evaluation. Psychological tests are best considered as sets of tasks or questions designed to elicit particular behaviors when presented in a standardized manner.

The salient characteristics of a good test are: (1) Validity, i.e., the test measures what it is supposed to measure, as determined by appropriate methods; (2) reliability, i.e., the consistency of results obtained over time with the same test and the same individual; and (3) appropriate normative data, i.e., individual test scores must be comparable to test data from other individuals or groups of a similar nature, representative of that population. In considering the validity of a test result, any discrepancies between formal test results and the child's customary behavior and daily activities should be duly noted and resolved.

Tests meeting the above requirements are acceptable for the determination of the conditions contained in these listings. The psychologist, psychiatrist, pediatrician, or other physician specialist administering the test must have a sound technical and professional understanding of the test and be able to evaluate the research documentation related to the intended application of the test.

Identical IQ scores obtained from different tests do not always reflect a similar degree of intellectual functioning. The IQ scores in listing 112.05 reflect values from tests of general intelligence that have a mean of 100 and a standard deviation of 15, e.g., the Weschsler series and the Revised Stanford-Binet scales. Thus, IQ's below 60 reflect a level of intellectual functioning below 99.5 percent of the general population, and IQ's of 70 and below are characteristic of approximately the lowest 2 percent of the general population. IQ's obtained from standardized tests that deviate significantly from a mean of 100 and standard deviation of 15 require conversion to the corresponding percentile rank in the general population so that the actual degree of impairment reflected by the IQ scores can be determined. In cases where more than one IQ is customarily derived from the test administered. e.g., where verbal, performance, and full

scale IQ's are provided, as on the Wechsler series, the lowest of these is used in conjunction with listing 112.05.

IQ test results must also be sufficiently current for accurate assessment under 112.05. Generally, the results of IQ tests tend to stabilize by the age of 16. Therefore, IQ test results obtained at age 16 or older should be viewed as a valid indication of the child's current status, provided they are compatible with the child's current behavior. IQ test results obtained between ages 7 and 16 should be considered current for 4 years when the tested IQ is less than 40, and for 2 years when the IQ is 40 or above. IQ test results obtained before age 7 are current for 2 years if the tested IQ is less than 40 and 1 year if at 40 or above.

Standardized intelligence test results are essential to the adjudication of all cases of mental retardation that are not covered under the provisions of listings 112.05A, 112.05B, and 112.05F. Listings 112.05A, 112.05B, and 112.05F may be the bases for adjudicating cases where the results of standardized intelligence tests are unavailable, e.g., where the child's young age or condition precludes formal standardized testing.

In conjunction with clinical examinations, sources may report the results of screening tests; i.e., tests used for gross determination of level of functioning. These tests do not have high validity and reliability and generally are not considered appropriate primary evidence for disability determinations. These screening instruments may be useful in uncovering potentially serious impairments, but generally must be supplemented by the use of formal, standardized psychological testing for the purposes of a disability determination, unless the determination is to be made on the basis of findings other than psychological test data; however, there will be cases in which the results of screening tests show such obvious abnormalities that further testing will clearly be unnecessary.

Where reference is made to developmental milestones, this is defined as the attainment of particular mental or motor skills at an age-appropriate level; i.e., the skills achieved by an infant or toddler sequentially and within a given time period in the motor and manipulative areas, in general understanding and social behavior, in self-feeding, dressing, and toilet training, and in language. This is sometimes expressed as a developmental quotient (DQ), the relation between developmental age and chronological age as determined by specific standardized measurements and observations. Such tests include, but are not limited to, the Cattell Infant Intelligence Scale, the Bayley Scales of Infant Development, and the Revised Stanford-Binet. Formal tests of the attainment of developmental milestones are generally used in the clinical setting for determination of the developmental status of infants and toddlers.

Formal psychological tests of cognitive functioning are generally in use for preschool children, for primary school children, and for adolescents except for those instances noted below.

Exceptions to formal standardized psychological testing may be considered when a psychologist, psychiatrist, pediatrician, or other physician specialist who is qualified by training and experience to perform such an evaluation is not readily available. In such instances, appropriate medical, historical, social, and other information must be reviewed in arriving at a determination.

Exceptions may also be considered in the case of ethnic/cultural minorities where the native language or culture is not principally English-speaking. In such instances, psychological tests that are culture-free, such as the Leiter International Performance Scale or the Scale of Multi-Culture Pluralistic Assessment (SOMPA) may be substituted for the standardized tests described above. Any required tests must be administered in the child's principal language. When this is not possible, appropriate medical, historical, social, and other information must be reviewed in arriving at a determination. Furthermore, in evaluating mental impairment in children from a different culture, the best indicator of severity is often the level of adaptive functioning and how the child performs activities of daily living and social functioning.

Neuropsychological testing refers to the administration of standardized tests that are reliable and valid with respect to assessing impairment in brain functioning. It is intended that the psychologist or psychiatrist using these tests will be able to evaluate the following functions: Attention/concentration, problem-solving, language, memory, motor, visual-motor and visual-perceptual, laterality, and general intelligence (if not previously obtained).

E. *Effect of Hospitalization or Residential Placement:* As with adults, children with mental disorders may be placed in a variety of structured settings outside the home as part of their treatment. Such settings include, but are not limited to, psychiatric hospitals, developmental disabilities facilities, residential treatment centers and schools, community-based group homes, and workshop facilities. The reduced mental demands of such structured settings may attenuate overt symptomatology and superficially make the child's level of adaptive functioning appear better than it is. Therefore, the capacity of the child to function outside highly structured settings must be considered in evaluating impairment severity. This is done by determining the degree to which the child can function (based upon age-appropriate expectations) independently, appropriaterly, effectively, and on a sustained basis outside the highly structured setting.

On the other hand, there may be a variety of causes for placement of a child in a structured setting which may or may not be directly related to impairment severity and functional ability. Placement in a structured setting in and of itself does not equate with a finding of disability. The severity of the impairment must be compared with the requirements of the appropriate listing.

F. *Effects of Medication:* Attention must be given to the effect of medication on the child's signs, symptoms, and ability to function. While psychoactive medications may control certain primary manifestations of a mental disorder, e.g., hallucinations, impaired attention, restlessness, or hyperactivity, such treatment may or may not affect the functional limitations imposed by the mental disorder. In cases where overt symptomatology is attenuated by the psychoactive medications, particular attention must be focused on the functional limitations which may persist. These functional limitations must be considered in assessing impairment severity.

Psychotropic medicines used in the treatment of some mental illnesses may cause drowsiness, blunted affect, or other side effects involving other body systems. Such side effects must be considered in evaluating overall impairment severity.

112.01 Category of Impairments, Mental

112.02 *Organic Mental Disorders:* Abnormalities in perception, cognition, affect, or behavior associated with dysfunction of the brain. The history and physical examination or laboratory tests, including psychological or neuropsychological tests, demonstrate or support the presence of an organic factor judged to be etiologically related to the abnormal mental state and associated deficit or loss of specific cognitive abilities, or affective changes, or loss of previously acquired functional abilities.

The required level of severity for these disorders is met when the requirements in both A and B are satisfied.

A. Medically documented persistence of at least one of the following:

1. Developmental arrest, delay or regression; or

2. Disorientation to time and place; or

3. Memory impairment, either short-term (inability to learn new information), intermediate, or long-term (inability to remember information that was known sometime in the past); or

4. Perceptual or thinking disturbance (e.g., hallucinations, delusions, illusions, or paranoid thinking); or

5. Disturbance in personality (e.g., apathy, hostility); or

6. Disturbance in mood (e.g., mania, depression); or

7. Emotional lability (e.g., sudden crying); or

8. Impairment of impulse control (e.g., disinhibited social behavior, explosive temper outbursts); or

9. Impairment of cognitive function, as measured by clinically timely standardized psychological testing; or

10. Disturbance of concentration, attention, or judgment;

AND

B. Select the appropriate age group to evaluate the severity of the impairment:

1. For older infants and toddlers (age 1 to attainment of age 3), resulting in at least one of the following:

a. Gross or fine motor development at a level generally acquired by children no more than one-half the child's chronological age, documented by:

(1) An appropriate standardized test; or

(2) Other medical findings (see 112.00C); or

b. Cognitive/communicative function at a level generally acquired by children no more than one-half the child's chronological age, documented by:

(1) An appropriate standardized test; or

(2) Other medical findings of equivalent cognitive/communicative abnormality, such as the inability to use simple verbal or nonverbal behavior to communicate basic needs or concepts; or

c. Social function at a level generally acquired by children no more than one-half the child's chronological age, documented by:

(1) An appropriate standardized test; or

(2) Other medical findings of an equivalent abnormality of social functioning, exemplified by serious inability to achieve age-appropriate autonomy as manifested by excessive clinging or extreme separation anxiety; or

d. Attainment of development or function generally acquired by children no more than two-thirds of the child's chronological age in two or more areas covered by a., b., or c., as measured by an appropriate standardized test or other appropriate medical findings.

2. For children (age 3 to attainment of age 18), resulting in at least two of the following;

a. Marked impairment in age-appropriate cognitive/communicative function, documented by medical findings (including consideration of historical and other information from parents or other individuals who have knowledge of the child, when such information is needed and available) and including, if necessary, the results of appropriate standardized psychological tests, or for children under age 6, by appropriate tests of language and communication; or

b. Marked impairment in age-appropriate social functioning, documented by history and medical findings (including consideration of information from parents or other individuals who have knowledge of the child, when such information is needed and available) and including, if necessary, the results of appropriate standardized tests; or

c. Marked impairment in personal/behavioral function, as evidenced by:

(1) Marked restriction of age-appropriate activities of daily living, documented by history and medical findings (including consideration of information from parents or other individuals who have knowledge of the child, when such information is needed and available) and including, if necessary, appropriate standardized tests; or

(2) Persistent serious maladaptive behaviors destructive to self, others, animals, or property, requiring protective intervention; or

d. Deficiencies of concentration, persistence, or pace resulting in frequent failure to complete tasks in a timely manner.

112.03 *Schizophrenic, Delusional (Paranoid), Schizoaffective, and Other Psychotic Disorders:* Onset of psychotic features, characterized by a marked disturbance of thinking, feeling, and behavior, with deterioration from a previous level of functioning or failure to achieve the expected level of social functioning.

The required level of severity for these disorders is met when the requirements in both A and B are satisfied.

A. Medically documented persistence, for at least 6 months, either continuous or intermittent, of one or more of the following:

1. Delusions or hallucinations; or

2. Catatonic, bizarre, or other grossly disorganized behavior; or

3. Incoherence, loosening of associations, illogical thinking, or poverty of content of speech; or

4. Flat, blunt, or inappropriate affect; or

5. Emotional withdrawal, apathy, or isolation;

AND

B. For older infants and toddlers (age 1 to attainment of age 3), resulting in at least one of the appropriate age-group criteria in paragraph B1 of 112.02; or, for children (age 3 to attainment of age 18), resulting in at least two of the appropriate age-group criteria in paragraph B2 of 112.02.

112.04 *Mood Disorders:* Characterized by a disturbance of mood (referring to a prolonged emotion that colors the whole psychic life, generally involving either depression or elation), accompanied by a full or partial manic or depressive syndrome.

The required level of severity for these disorders is met when the requirements in both A and B are satisfied.

A. Medically documented persistence, either continuous or intermittent, of one of the following:

1. Major depressive syndrome, characterized by at least five of the following, which must include either depressed or irritable mood or markedly diminished interest or pleasure:

a. Depressed or irritable mood; or

b. Markedly diminished interest or pleasure in almost all activities; or

c. Appetite or weight increase or decrease, or failure to make expected weight gains; or

d. Sleep disturbance; or

e. Psychomotor agitation or retardation; or

f. Fatigue or loss of energy; or

g. Feelings of worthlessness or guilt; or

h. Difficulty thinking or concentrating; or

i. Suicidal thoughts or acts; or

j. Hallucinations, delusions, or paranoid thinking;

OR

2. Manic syndrome, characterized by elevated, expansive, or irritable mood, and at least three of the following:

a. Increased activity or psychomotor agitation; or

b. Increased talkativeness or pressure of speech; or

c. Flight of ideas or subjectively experienced racing thoughts; or

d. Inflated self-esteem or grandiosity; or

e. Decreased need for sleep; or

f. Easy distractibility; or

g. Involvement in activities that have a high potential of painful consequences which are not recognized; or

h. Hallucinations, delusions, or paranoid thinking;

OR

3. Bipolar or cyclothymic syndrome with a history of episodic periods manifested by the full symptomatic picture of both manic and depressive syndromes (and currently or most recently characterized by the full or partial symptomatic picture of either or both syndromes);

AND

B. For older infants and toddlers (age 1 to attainment of age 3), resulting in at least one of the appropriate age-group criteria in paragraph B1 of 112.02; or, for children (age 3 to attainment of age 18), resulting in at least two of the appropriate age-group criteria in paragraph B2 of 112.02.

112.05 *Mental Retardation:* Characterized by significantly subaverage general intellectual functioning with deficits in adaptive functioning.

The required level of severity for this disorder is met when the requirements in A, B, C, D, E, or F are satisfied.

A. For older infants and toddlers (age 1 to attainment of age 3), resulting in at least one of the appropriate age-group criteria in paragraph B1 of 112.02; or, for children (age 3 to attainment of age 18), resulting in at least two of the appropriate age-group criteria in paragraph B2 of 112.02.

OR

B. Mental incapacity evidenced by dependence upon others for personal needs (grossly in excess of age-appropriate dependence) and inability to follow directions such that the use of standardized measures of intellectual functioning is precluded;

OR

C. A valid verbal, performance, or full scale IQ of 59 or less:

OR

D. A valid verbal, performance, or full scale IQ of 60 through 70 and a physical or other mental impairment imposing additional and significant limitation of function;

OR

E. A valid verbal, performance, or full scale IQ of 60 through 70 and:

1. For older infants and toddlers (age 1 to attainment of age 3), resulting in attainment of development or function generally acquired by children no more than two-thirds of the child's chronological age in either paragraphs B1a or B1c of 112.02; or

2. For children (age 3 to attainment of age 18), resulting in at least one of paragraphs B2b or B2c or B2d of 112.02;

OR

F. Select the appropriate age group:

1. For older infants and toddlers (age 1 to attainment of age 3), resulting in attainment of development or function generally acquired by children no more than two-thirds of the child's chronological age in paragraph B1b of 112.02, and a physical or other mental impairment imposing additional and significant limitations of function;

OR

2. For children (age 3 to attainment of age 18), resulting in the satisfaction of 112.02B2a, and a physical or other mental impairment imposing additional and significant limitations of function.

112.06 *Anxiety Disorders:* In these disorders, anxiety is either the predominant disturbance or is experienced if the individual attempts to master symptoms, e.g., confronting the dreaded object or situation in a phobic disorder, attempting to go to school in a separation anxiety disorder, resisting the obsessions or compulsions in an obsessive compulsive disorder, or confronting strangers or peers in avoidant disorders.

The required level of severity for these disorders is met when the requirements in both A and B are satisfied.

A. Medically documented findings of at least one of the following:

1. Excessive anxiety manifested when the child is separated, or separation is threatened, from a parent or parent surrogate; or

2. Excessive and persistent avoidance of strangers; or

3. Persistent unrealistic or excessive anxiety and worry (apprehensive expectation), accompanied by motor tension, autonomic hyperactivity, or vigilance and scanning; or

4. A persistent irrational fear of a specific object, activity, or situation which results in a compelling desire to avoid the dreaded object, activity, or situation; or

5. Recurrent severe panic attacks, manifested by a sudden unpredictable onset of intense apprehension, fear, or terror, often with a sense of impending doom, occurring on the average of at least once a week; or

6. Recurrent obsessions or compulsions which are a source of marked distress; or

7. Recurrent and intrusive recollections of a traumatic experience, including dreams, which are a source of marked distress;

AND

B. For older infants and toddlers (age 1 to attainment of age 3), resulting in at least one of the appropriate age-group criteria in paragraph B1 of 112.02; or, for children (age 3 to attainment of age 18), resulting in at least two of the appropriate age-group criteria in paragraph B2 of 112.02.

112.07 *Somatoform, Eating, and Tic Disorders:* Manifested by physical symptoms for which there are no demonstrable organic findings or known physiologic mechanisms; or eating or tic disorders with physical manifestations.

The required level of severity for these disorders is met when the requirements in both A and B are satisfied.

A. Medically documented findings of one of the following:

1. An unrealistic fear and perception of fatness despite being underweight; and persistent refusal to maintain a body weight which is greater then 85 percent of the average weight for height and age, as shown in the most recent edition of the *Nelson Textbook of Pediatrics*, Richard E. Behrman and Victor C. Vaughan, III, editors, Philadelphia: W.B. Saunders Company; or

2. Persistent and recurrent involuntary, repetitive, rapid, purposeless motor movements affecting multiple muscle groups with multiple vocal tics; or

3. Persistent nonorganic disturbance of one of the following:

a. Vision; or

b. Speech; or

c. Hearing; or

d. Use of a limb; or

e. Movement and its control (e.g., coordination disturbance, psychogenic seizures); or

f. Sensation (diminished or heightened); or

g. Digestion or elimination; or

4. Preoccupation with a belief that one has a serious disease or injury;

AND

B. For older infants and toddlers (age 1 to attainment of age 3), resulting in at least one of the appropriate age-group criteria in paragraph B1 of 112.02; or, for children (age 3 to attainment of age 18), resulting in at least two of the appropriate age-group criteria in paragraph B2 of 112.02.

112.08 *Personality Disorders:* Manifested by pervasive, inflexible, and maladaptive personality traits, which are typical of the child's long-term functioning and not limited to discrete episodes of illness.

The required level of severity for these disorders is met when the requirements in both A and B are satisfied.

A. Deeply ingrained, maladaptive patterns of behavior, associated with one of the following:

1. Seclusiveness or autistic thinking: or

2. Pathologically inappropriate suspiciousness or hostility; or

3. Oddities of thought, perception, speech, and behavior; or

4. Persistent disturbances of mood or affect; or

5. Pathological dependence, passivity, or aggressiveness; or

6. Intense and unstable interpersonal relationships and impulsive and exploitative behavior; or

7. Pathological perfectionism and inflexibility;

AND

B. For older infants and toddlers (age 1 to attainment of age 3), resulting in at least one of the appropriate age-group criteria in paragraph B1 of 112.02; or, for children (age 3 to attainment of age 18), resulting in at least two of the appropriate age-group criteria in paragraph B2 of 112.02.

112.09 *Psychoactive Substance Dependence Disorders:* Manifested by a cluster of cognitive, behavioral, and physiologic symptoms that indicate impaired control of psychoactive substance use with continued use of the substance despite adverse consequences.

The required level of severity for these disorders is met when the requirements in both A and B are satisfied.

A. Medically documented findings of at least four of the following:

1. Substance taken in larger amounts or over a longer period than intended and a great deal of time is spent in recovering from its effects; or

2. Two or more unsuccessful efforts to cut down or control use; or

3. Frequent intoxication or withdrawal symptoms interfering with major role obligations; or

4. Continued use despite persistent or recurring social, psychological, or physical problems; or

5. Tolerance, as characterized by the requirement for markedly increased amounts of substance in order to achieve intoxication; or

6. Substance taken to relieve or avoid withdrawal symptoms;

AND

B. For older infants and toddlers (age 1 to attainment of age 3), resulting in at least one of the appropriate age-group criteria in paragraph B1 of 112.02; or, for children (age 3 to attainment of age 18), resulting in at least two of the appropriate age-group criteria in paragraph B2 of 112.02

112.10 *Autistic Disorder and Other Pervasive Developmental Disorders:* Characterized by qualitative deficits in the development of reciprocal social interaction, in the development of verbal and nonverbal communication skills, and in imaginative activity. Often, there is a markedly restricted repertoire of activities and interests, which frequently are stereotyped and repetitive.

The required level of severity for these disorders is met when the requirements in both A and B are satisfied.

A. Medically documented findings of the following:

1. For autistic disorder, all of the following:

a. Qualitative deficits in the development of reciprocal social interaction; and

b. Qualitative deficits in verbal and nonverbal communication and in imaginative activity; and

c. Markedly restricted repertoire of activities and interests;

OR

2. For pervasive developmental disorders, both of the following:

a. Qualitative deficits in the development of social interaction; and

b. Qualitative deficits in verbal and nonverbal communication and in imaginative activity;

AND

B. For older infants and toddlers (age 1 to attainment of age 3), resulting in at least one of the appropriate age-group criteria in paragraph B1 of 112.02; or, for children (age 3 to attainment of age 18), resulting in at least two of the appropriate age-group criteria in paragraph B2 of 112.02.

112.11 *Attention Deficit Hyperactivity Disorder:* Manifested by developmentally inappropriate degrees of inattention, impulsiveness, and hyperactivity.

The required level of severity for these disorders is met when the requirements in both A and B are satisfied.

A. Medically documented findings of all three of the following:

1. Marked inattention; and

2. Marked impulsiveness; and

3. Marked hyperactivity;

AND

B. For older infants and toddlers (age 1 to attainment of age 3), resulting in at least one of the appropriate age-group criteria in paragraph B1 of 112.02; or, for children (age 3 to attainment of age 18), resulting in at least two of the appropriate age-group criteria in paragraph B2 of 112.02.

112.12 *Developmental and Emotional Disorders of Newborn and Younger Infants (Birth to attainment of age 1);* Developmental or emotional disorders of infancy are evidenced by a deficit or lag in the areas of motor, cognitive/communicative, or social functioning. These disorders may be related either to organic or to functional factors or to a combination of these factors.

The required level of severity for these disorders is met when the requirements of A, B, C, D, or E are satisfied.

A. Cognitive/communicative functioning generally acquired by children no more than one-half the child's chronological age, as documented by appropriate medical findings (e.g., in infants 0-6 months, markedly diminished variation in the production or imitation of sounds and severe feeding abnormality, such as problems with sucking, swallowing, or chewing) including, if necessary, a standardized test;

OR

B. Motor development generally acquired by children no more than one-half the child's chronological age, documented by appropriate medical findings, including if necessary, a standardized test:

OR

C. Apathy, over-excitability, or fearfulness, demonstrated by an absent or grossly excessive response to one of the following:

1. Visual stimulation; or

2. Auditory stimulation; or

3. Tactile stimulation;

OR

D. Failure to sustain social interaction on an ongoing, reciprocal basis as evidenced by:

1. Inability by 6 months to participate in vocal, visual, and motoric exchanges (including facial expressions); or

2. Failure by 9 months to communicate basic emotional responses, such as cuddling or exhibiting protest or anger; or

3. Failure to attend to the caregiver's voice or face or to explore an inanimate object for a period of time appropriate to the infant's age;

OR

E. Attainment of development or function generally acquired by children no more than two-thirds of the child's chronological age in two or more areas (i.e., cognitive/communicative, motor, and social), documented by appropriate medical findings, including if necessary, standardized testing.

113.00 Neoplastic Diseases, Malignant

A. *Introduction* Determination of disability in the growing and developing child with a malignant neoplastic disease is based upon the combined effects of:

1. The pathophysiology, histology, and natural history of the tumor; and

2. The effects of the currently employed aggressive multimodal therapeutic regimens.

Combinations of surgery, radiation, and chemotherapy or prolonged therapeutic schedules impart significant additional morbidity to the child during the period of greatest risk from the tumor itself. This period of highest risk and greatest therapeutically-induced morbidity defines the limits of disability for most of childhood neoplastic disease.

B. *Documentation.* The diagnosis of neoplasm should be established on the basis of symptoms, signs, and laboratory findings. The site of the primary,

recurrent, and metastatic lesion must be specified in all cases of malignant neoplastic diseases. If an operative procedure has been performed, the evidence should include a copy of the operative note and the report of the gross and microscopic examination of the surgical specimen, along with all pertinent laboratory and X-ray reports. The evidence should also include a recent report directed especially at describing whether there is evidence of local or regional recurrence, soft part or skeletal metastases, and significant post therapeutic residuals.

C. *Malignant solid tumors***,** as listed under 113.03, include the histiocytosis syndromes except for solitary eosinophilic granuloma. Thus, 113.03 should not be used for evaluating brain tumors (see 111.05) or thyroid tumors, which must be evaluated on the basis of whether they are controlled by prescribed therapy.

D. *Duration of disability* from malignant neoplastic tumors is included in 113.02 and 113.03. Following the time periods designated in these sections, a documented diagnosis itself is no longer sufficient to establish a severe impairment. The severity of a remaining impairment must be evaluated on the basis of the medical evidence.

113.01 Category of Impairments, Neoplastic Diseases - Malignant

113.02 *Lymphoreticular Malignant Neoplasms*

A. Hodgkin's Disease with progressive disease not controlled by prescribed therapy; or

B. Non-Hodgkin's lymphoma. Consider under a disability:

1. For 2 1/2 years from the time of initial diagnosis, or

2. For 2 1/2 years from the time of recurrence of active disease.

113.03 *Malignant Solid Tumors*. Consider under a disability:

A. For 2 years from the time of initial diagnosis; or

B. For 2 years from the time of recurrence of active disease.

113.04 *Neuroblastoma.* With one of the following:

A. Extension across the midline; or

B. Distant metastases; or

C. Recurrance; or

D. Onset at age 1 year or older.

113.05 *Retinoblastoma.* With one of the following:

A. Bilateral involvement; or

B. Metastases; or

C. Extension beyond the orbit; or

D. Recurrence.

114.00 Immune System

A. Listed disorders include impairments involving deficiency of one or more components of the immune system (i.e., antibody-producing B cells; a number of different types of cells associated with cell-mediated immunity including T-lymphocytes, macrophages and monocytes; and components of the complement system).

B. Dysregulation of the immune system may result in the development of a connective tissue disorder. Connective tissue disorders include several chronic multisystem disorders that differ in their clinical manifestation, course, and outcome. These disorders are described in Part A, 14.00B.

Some of the features of connective tissue disorders in children may differ from the features in adults. When the clinical features are the same as that seen in adults, the principles and concepts in part A, 14.00B apply.

The documentation needed to establish the existence of a connective tissue disorder is medical history, physical examination, selected laboratory studies, medically acceptable imaging techniques and, in some instances, tissue biopsy. However, the Social Security Administration will not purchase diagnostic tests or procedures that may involve significant risk, such as biopsies or angiograms. Generally, the existing medical evidence will contain this information.

In addition to the limitations caused by the connective tissue disorder per se, the chronic adverse effects of treatment (e.g., corticosteroid-related ischemic necrosis of bone) may result in functional loss.

A longitudinal clinical record of at least 3 months demonstrating active disease despite prescribed treatment during this period with the expectation that the disease will remain active for 12 months is necessary for assessment of severity and duration of impairment.

In children the impairment may affect growth, development, attainment of age-appropriate skills, and performance of age-appropriate activities. The limitations may be the result of loss of function or failure in a single organ or body system, or a lesser degree of functional loss in two or more organs/body systems that, in combination with significant constitutional symptoms and signs of severe fatigue, fever, malaise, and weight loss, results in listing-level limitations. We use the term “severe” in these listings to describe medical severity; the term does not have the same meaning as it does when we use it in connection with a finding at the second step of the sequential evaluation processes in Sections 404.1520, 416.920, and 416.924.

C. Allergies, growth impairments and Kawasaki disease.

1. Allergic disorders (e.g., asthma or atopic dermatitis) are discussed and evaluated under the appropriate listing of the affected body system.

2. If growth is affected by the disorder or its treatment by immunosuppressive drugs, 100.00 may apply.

3. Kawasaki disease, also known as mucocutaneous lymph node syndrome, is characterized by multisystem manifestations, but significant functional impairment is usually due to disease of the coronary arteries, which should be evaluated under 104.00.

D. Human immunodeficiency virus (HIV) infection.

1. HIV infection is caused by a specific retrovirus and may be characterized by susceptibility to one or more opportunistic diseases, cancers, or other conditions, as described in 114.08. Any child with HIV infection, including one with a diagnosis of acquired immunodeficiency syndrome (AIDS), may be found disabled under this listing if his or her impairment meets any of the criteria in 114.08 or is of equivalent severity to any impairment in 114.08.

2. Definitions. In 114.08, the terms "resistant to treatment," "recurrent," and "disseminated" have the same general meaning as used by the medical community. The precise meaning of any of these terms will depend upon the specific disease or condition in question, the body system affected, the usual course of the disorder and its treatment, and the other circumstances of the case.

"Resistant to treatment" means that a condition did not respond adequately to an appropriate course of treatment. Whether a response is adequate, or a course of treatment appropriate, will depend on the facts of the particular case.

"Recurrent" means that a condition that responded adequately to an appropriate course of treatment has returned after a period of remission or regression. The extent of response (or remission) and the time periods involved will depend on the facts of the particular case.

"Disseminated" means that a condition is spread widely over a considerable area or body system(s). The type and extent of the spread will depend on the specific disease.

3. Documentation of HIV infection in children. The medical evidence must include documentation of HIV infection. Documentation may be by laboratory evidence or by other generally acceptable methods consistent with the prevailing state of medical knowledge and clinical practice.

a. Documentation of HIV infection in children by definitive diagnosis. A definitive diagnosis of HIV infection is documented by one or more of the following laboratory tests:

i] For a child 24 months of age or older, a serum specimen that contains HIV antibodies. HIV antibodies are usually detected by a screening test. The most commonly used screening test is the ELISA. Although this test is highly sensitive, it may yield false positive results. Therefore, positive results from an ELISA must be confirmed by a more definitive test (e.g., Western Blot, immunofluorescence assay). (See paragraph b, below, for information about HIV antibody testing in children younger than 24 months of age).

ii] A specimen that contains HIV antigen (e.g., serum specimen, lymphocyte culture, or cerebrospinal fluid (CSF) specimen).

iii] An imunoglobulin A(lgA) serological assay specific for HIV.

iv] Other test(s) that are highly specific for detection of HIV in children (e.g., polymerase chain reaction (PCR)), or that are acceptable methods of detection consistent with the prevailing state of medical knowledge.

When laboratory testing for HIV infection has been performed, every reasonable effort must be made to obtain reports of the results of that testing.

b. Other acceptable documentation of HIV infection in children.

As noted in paragraph a, above, HIV infection is not documented in children under 24 months of age by a serum specimen containing HIV antibodies. This is because women with HIV infection often transfer HIV antibodies to their newborns. The mother's antibodies can persist in the infant for up to 24 months, even if the infant is not HIV-infected. Only 20 to 30 percent of such infants are actually infected. Therefore, the presence of serum HIV antibodies alone does not establish the presence of HIV infection in a child under 24 months of age. However, the presence of HIV antibodies accompanied by evidence of significantly depressed T-helper lymphocytes (CD4), an abnormal CD4/CD8 ratio, or abnormal immunoglobulin G (IgG) may be used to document HIV infection in a child under 24 months of age, even though such testing is not a basis for a definitive diagnosis.

For children from birth to the attainment of 24 months of age who have tested positive for HIV antibodies (see D3a above), HIV infection may be documented by one or more of the following:

i.] For an infant 12 months of age or less, a CD4 (T4) count of 1500/mm^3 or less, or a CD4 count less than or equal to 20 percent of total lymphocytes.

ii.] For an infant from 12 to 24 months of age, a CD4 (T4) count of 750/mm^3 or less, or a CD4 count less than or equal to 20 percent of total lymphocytes.

iii.] An abnormal CD4/CD8 ratio.

iv.] An IgG significantly greater than or less than the normal range for age.

HIV infection in children may also be documented without the definitive laboratory evidence described in paragraph a, or the other laboratory evidence discussed above, provided that such documentation is consistent with the prevailing state of medical knowledge and clinical practice and is consistent with the other evidence. If such laboratory evidence is not available, HIV infection may be documented by the medical history, clinical and laboratory findings, and diagnosis(es) indicated in the medical evidence. For example, a diagnosis of HIV infection in children will be accepted without definitive laboratory evidence if the child has an opportunistic disease (e.g., Pneumocystis carinii pneumonia (PCP)) predictive of a defect in cell-mediated immunity, and there is no other known cause of diminished resistance to that disease (e.g., long-term steroid treatment, lymphoma). In such cases, every reasonable effort must be made to obtain full details of the history, medical findings, and results of testing.

4. Documentation of the manifestations of HIV infection in children. The medical evidence must also include documentation of the manifestations of HIV infection in children. Documentation may be by laboratory evidence or by other

generally acceptable methods consistent with the prevailing state of medical knowledge and clinical practice.

a. Documentation of the manifestations of HIV infection in children by definitive diagnosis.

The definitive method of diagnosing opportunistic diseases or conditions that are manifestations of HIV infection in children is by culture, serological test, or microscopic examination of biopsied tissue or other material (e.g., bronchial washings). Therefore, every reasonable effort must be made to obtain specific laboratory evidence of an opportunistic disease or other condition whenever this information is available. If a histological or other test has been performed, the evidence should include a copy of the appropriate report. If the report is not obtainable, the summary of hospitalization or a report from the treating source should include details of the findings and results of the diagnostic studies (including radiographic studies) or microscopic examination of the appropriate tissues or body fluids.

Although a reduced CD4 lymphocyte count in a child may show that there is an increased susceptibility to opportunistic infections and diseases, that alone does not establish the presence, severity, or functional effects of a manifestation of HIV infection in a child.

b. Other acceptable documentation of the manifestations of HIV infection in children.

Manifestations of HIV infection in children may also be documented without the definitive laboratory evidence described in paragraph a, provided that such documentation is consistent with the prevailing state of medical knowledge and clinical practice and is consistent with the other evidence. If no definitive laboratory evidence is available, manifestations of HIV infection may be documented by medical history, clinical and laboratory findings, and diagnosis(es) indicated in the medical evidence. In such cases, every reasonable effort must be made to obtain full details of the history, medical findings, and results of testing.

Documentation of cytomegalovirus (CMV) disease (114.08D) presents special problems because diagnosis requires identification of viral inclusion bodies or a positive culture from the affected organ, and the absence of any other infectious agent. A positive serology test identifies infection with the virus, but does not confirm a disease process. With the exception of chorioretinitis (which may be diagnosed by an ophthalmologist), documentation of CMV disease requires confirmation by biopsy or other generally acceptable methods consistent with the prevailing state of medical knowledge and clinical practice.

5. HIV infection in children. The clinical manifestation and course of disease in children who become infected with HIV perinatally or in the first 6 years of life may differ from that in older children and adults. In addition, survival times are shorter for children infected in the first year of life compared to those who become infected as older children or as adults. Infants may present with failure to thrive or pneumocystis carinii pneumonia (PCP); young children may present with recurrent infections, neurological problems, or developmental

abnormalities. Older children may also exhibit neurological abnormalities, such as HIV encephalopathy, or failure to thrive.

The methods of identifying and evaluating neurological abnormalities may vary depending on a child's age. For example, in an infant, impaired brain growth can be documented by a decrease in the growth rate of the head. In older children, impaired brain growth can be documented by brain atrophy on a CAT scan. Neurological abnormalities can also be observed in a younger child in the loss of previously acquired, or marked delays in achieving, developmental milestones. In an older child, this type of neurological abnormality would generally be demonstrated by the loss of previously acquired intellectual abilities. Although loss of previously acquired intellectual abilities can be documented by a decrease in intelligence quotient (IQ) scores or demonstrated if a child forgets information he or she previously learned, it can also be shown if the child is unable to learn new information. This could include the sudden acquisition of a new learning disability.

Children with HIV infection may contract any of a broad range of bacterial infections. Certain major infections caused by pyogenic bacteria, e.g., some pneumonias, can be severely limiting, especially in pre-adolescent children. These major bacterial infections should be evaluated under 114.08A5, which requires two or more such infections within a 2-year period. Although 114.08A5 applies only to children less than 13 years of age, an older child may be found to have an impairment of equivalent severity if the circumstances of the case warrant (e.g., delayed puberty).

Otherwise, bacterial infections are evaluated under 114.08A6. The criteria of the listing are met if one or more bacterial infection(s) occurs and requires hospitalization or intravenous antibiotic treatment 3 or more times in 1 year. Pelvic inflammatory disease in older female children should be evaluated under multiple or recurrent bacterial infections (114.08A6).

6. Evaluation of HIV infection in children. The criteria in 114.08 do not describe the full spectrum of diseases or conditions manifested by children with HIV infection. As in any case, consideration must be given to whether a child's impairment(s) meets or equals in severity any other listing in appendix 1 of subpart P (e.g., a neoplastic disorder listed in 113.00ff). Although 114.08 includes cross-references to other listings for the more common manifestations of HIV infection, additional listings may also apply.

In addition, the impact of all impairments, whether or not related to the HIV infection, must be considered. Children with HIV infection may manifest signs and symptoms of a mental impairment (e.g., anxiety, depression), or of another physical impairment. Medical evidence should include documentation of all physical and mental impairments, and the impairment(s) should be evaluated not only under the relevant listing(s) in 114.08, but under any other appropriate listing(s).

It is also important to remember that children with HIV infection, like all others, are evaluated under the full sequential evaluation process described in Section 416.924. If a child with HIV infection is working and engaging in substantial gainful activity (SGA), or does not have a severe impairment, the case will be decided at the first or second step of the sequential evaluation process, and does

not require evaluation under these listings. For a child with HIV infection who is not engaging in SGA and has a severe impairment, but whose impairment(s) does not meet the criteria of a listing, consideration will be given to whether the child's impairment or combination of impairments is either medically or functionally equivalent in severity to any listed impairment. If the child's impairment or impairments do not meet or equal a listing in severity, evaluation must proceed through the final step(s) of the sequential evaluation process (or, as appropriate, the steps in the medical improvement review standard) before any conclusion can be reached on the issue of disability.

7. Effect of treatment. Medical treatment must be considered in terms of its effectiveness in ameliorating the signs, symptoms, and laboratory abnormalities of the specific disorder, or of the HIV infection itself (e.g. antiretroviral agents) and in terms of any side effects of treatment that may further impair the child.

Response to treatment and adverse or beneficial consequences of treatment may vary widely. For example, a child with HIV infection who develops otitis media may respond to the same antibiotic regimen used in treating children without HIV infection, but another child with HIV infection may not respond to the same regimen. Therefore, each case must be considered on an individual basis, along with the effects of treatment on the child's ability to function.

A specific description of the drugs or treatment given (including surgery), dosage, frequency of administration, and a description of the complications or response to treatment should be obtained. The effects of treatment may be temporary or long-term. As such, the decision regarding the impact of treatment should be based on a sufficient period of treatment to permit proper consideration.

8. Functional criteria. Paragraph O of 114.08 establishes standards for evaluating manifestations of HIV infection that do not meet the requirements listed in 114.08A-N. Paragraph O is applicable for manifestations that are not listed in 114.08A-N, as well as those listed in 114.08A-N that do not meet the criteria of any of the rules in 114.08A-N.

For children with HIV infection evaluated under 114.08O, listing-level severity will be assessed in terms of the functional limitations imposed by the impairment. The full impact of signs, symptoms, and laboratory findings on the child's ability to function must be considered. Important factors to be considered in evaluating the functioning of children with HIV infection include, but are not limited to: symptoms, such as fatigue and pain; characteristics of the illness, such as the frequency and duration of manifestations or periods of exacerbation and remission in the disease course; and the functional impact of treatment for the disease, including the side effects of medication.

To meet the criteria in 114.08O, a child with HIV infection must demonstrate a level of restriction in either one or two (depending on the child's age) of the general areas of functioning applicable to the child's age group. (See 112.00C for additional discussion of these areas of functioning).

114.01 Category of Impairments, Immune System

114.02 *Systemic lupus erythematosus*. Documented as described in 14.00B1 and 114.00B, with:

A. One of the following:

1. Growth impairment, as described under the criteria in 100.00ff; or

2. Musculoskeletal involvement, as described under the criteria in 101.00ff; or

3. Muscle involvement, as described under the criteria in 14.05; or

4. Ocular involvement, as described under the criteria in 102.00ff; or

5. Respiratory involvement, as described under the criteria in 103.00ff; or

6. Cardiovascular involvement, as described under the criteria in 104.00ff or 14.04D; or

7. Digestive involvement, as described under the criteria in 105.00ff; or

8. Renal involvement, as described under the criteria in 106.00ff; or

9. Hematologic involvement, as described under the criteria in 107.00ff; or

10. Skin involvement, as described under the criteria in 8.00ff; or

11. Endocrine involvement, as described under the criteria in 109.00ff; or

12. Neurological involvement, as described under the criteria in 111.00ff; or

13. Mental involvement, as described under the criteria in 112.00ff.

or

B. Lesser involvement of two or more organs/body systems listed in paragraph A, with significant, documented, constitutional symptoms and signs of severe fatigue, fever, malaise, and weight loss. At least one of the organs/body systems must be involved to at least a moderate level of severity.

114.03 *Systemic vasculitis.* Documented as described in 14.03 or, if growth impairment, as described under the criteria in 100.00ff.

114.04 *Systemic sclerosis and scleroderma.* Documented as described in 14.00B3 and 114.00B, and:

A. As described under the criteria in 14.04 or, if growth impairment, as described under the criteria in 100.00ff.

or

B. Linear scleroderma, with one of the following:

1. Fixed valgus or varus deformities of both hands or both feet; or

2. Marked destruction or marked atrophy of an extremity; or

3. Facial disfigurement from hypoplasia of the mandible, maxilla, or zygoma resulting in an impairment as described under the criteria in 112.00ff; or

4. Seizure disorder, as described under the criteria in 111.00ff.

114.05 *Polymyositis or dermatomyositis.* Documented as described in 14.00B4 and 114.00B, and:

A. As described under the criteria in 14.05.

or

B. With one of the following:

1. Multiple joint contractures; or

2. Diffuse cutaneous calcification with formation of an exoskeleton; or

3. Systemic vasculitis as described under the criteria in 14.03.

114.06 *Undifferentiated connective tissue disorder*. As described under the criteria in 114.02 or 114.04.

114.07 *Congenital immune deficiency disease*.

A. Hypogammaglobulinemia or dysgammaglobulinemia, with:

1. Documented, recurrent severe infections occuring 3 or more times within a 5-month period; or

2. An associated disorder such as growth retardation, chronic lung disease, collagen disorder or tumor. Evaluate according to the appropriate body system listing.

or

B. Thymic dysplastic syndromes (such as Swiss, diGeorge).

114.08 *Human immunodeficiency virus (HIV) infection.* With documentation as described in 114.00D3 and one of the following:

A. Bacterial infections:

1. Mycobacterial infection (e.g., caused by M. avium-intracellulare, M. kansasii, or M. tuberculosis) at site other than the lungs, skin, or cervical or hilar lymph nodes; or pulmonary tuberculosis resistant to treatment; or

2. Nocardiosis; or

3. Salmonella bacteremia, recurrent non-typhoid; or

4. Syphilis or neurosyphilis - evaluate sequelae under the criteria for the affected body system (e.g., 102.00 Special Senses and Speech, 104.00 Cardiovascular System, 111.00 Neurological); or

5. In a child less than 13 years of age, multiple or recurrent pyogenic bacterial infection(s) of the following types: sepsis, pneumonia, meningitis, bone or joint infection, or abscess of an internal organ or body cavity (excluding otitis media or superficial skin or mucosal abscesses) occurring 2 or more times in 2 years; or

6. Other multiple or recurrent bacterial infection(s), including pelvic inflammatory disease, requiring hospitalization or intravenous antibiotic treatment 3 or more times in 1 year.

or

B. Fungal infections:

1. Aspergillosis; or

2. Candidiasis, at a site other than the skin, urinary tract, intestinal tract, or oral or vulvovaginal mucous membranes; or candidiasis involving the esophagus, trachea, bronchi, or lungs; or

3. Coccidioidomycosis, at a site other than the lungs or lymph nodes; or

4. Cryptococcosis, at a site other than the lungs (e.g., cryptococcal meningitis); or

5. Histoplasmosis, at a site other than the lungs or lymph nodes; or

6. Mucormycosis.

or

C. Protozoan or helminthic infections:

1. Cryptosporidiosis, isosporiasis, or microsporidiosis, with diarrhea lasting for 1 month or longer; or

2. Pneumocystis carinii pneumonia or extrapulmonary pneumocystis carinii infection; or

3. Strongyloidiasis, extra-intestinal; or

4. Toxoplasmosis of an organ other then the liver, spleen, or lymph nodes.

or

D. Viral infections:

1. Cytomegalovirus disease (documented as described in 114.00D4b) at a site other than the liver, spleen, or lymph nodes; or

2. Herpes simplex virus causing:

a. Mucocutaneous infection (e.g., oral, genital, perianal) lasting for 1 month or longer; or

b. Infection at a site other than the skin or mucous membranes (e.g., bronchitis, pneumonitis, esophagitis, or encephalitis); or

c. Disseminated infection; or

3. Herpes zoster, either disseminated or with multidermatomal eruptions that are resistant to treatment; or

4. Progressive multifocal leukoencephalopathy; or

5. Hepatitis, as described under the criteria in 105.05.

or

E. Malignant neoplasms:

1. Carcinoma of the cervix, invasive, FIGO stage II and beyond; or

2. Kaposi's sarcoma with:

a. Extensive oral lesions; or

b. Involvement of the gastrointestinal tract, lungs, or other visceral organs; or

c. Involvement of the skin or mucous membranes, as described under the criteria in 114.08F; or

3. Lymphoma (e.g., primary lymphoma of the brain, Burkitt's lymphoma, immunoblastic sarcoma, other Non-Hodgkins lymphoma, Hodgkin's disease); or

4. Squamous cell carcinoma of the anus.

or

F. Conditions of the skin or mucous membranes (other than described in B2, D2, or D3, above), with extensive fungating or ulcerating lesions not responding to treatment (e.g., dermatological conditions such as eczema or psoriasis, vulvovaginal or other mucosal candida, condyloma caused by human papillomavirus, genital ulcerative disease), or evaluate under the criteria in 8.00ff.

or

G. Hematologic abnormalities:

1. Anemia, as described under the criteria in 7.02; or

2. Granulocytopenia, as described under the criteria in 7.15; or

3. Thrombocytopenia, as described under the criteria in 107.06 or 7.06.

or

H. Neurological manifestations of HIV infection (e.g., HIV encephalopathy, peripheral neuropathy), as described under the criteria in 111.00ff, or resulting in one or more of the following:

1. Loss of previously acquired, or marked delay in achieving, developmental milestones or intellectual ability (including the sudden acquisition of a new learning disability); or

2. Impaired brain growth (acquired microcephaly or brain atrophy - see 114.00D5); or

3. Progressive motor dysfunction affecting gait and station or fine and gross motor skills.

or

I. Growth disturbance, with:

1. An involuntary weight loss (or failure to gain weight at an appropriate rate for age) resulting in a fall of 15 percentiles from established growth curve (on standard growth charts) that persists for 2 months or longer; or

2. An involuntary weight loss (or failure to gain weight at an appropriate rate for age) resulting in a fall to below the third percentile from established growth curve (on standard growth charts) that persists for 2 months or longer; or

3. Involuntary weight loss greater than 10 percent of baseline that persists for 2 months or longer; or

4. Growth impairment as described under the criteria in 100.00ff.

or

J. Diarrhea, lasting for 1 month or longer, resistant to treatment, and requiring intravenous hydration, intravenous alimentation, or tube feeding.

or

K. Cardiomyopathy, as described under the criteria in 104.00ff or 11.04.

or

L. Lymphoid interstitial pneumonia/pulmonary lymphoid hyperplasia (LIP/PLH complex), with respiratory symptoms that significantly interfere with age-appropriate activities, and that cannot be controlled by prescribed treatment.

or

M. Nephropathy, as described under the criteria in 106.00ff.

or

N. One or more of the following infections (other than described in A-M, above), resistant to treatment or requiring hospitalization or intravenous treatment 3 or more times in 1 year (or evaluate sequelae under the criteria for the affected body system).

1. Sepsis; or

2. Meningitis; or

3. Pneumonia; or

4. Septic arthritis; or

5. Endocarditis; or

6. Radiographically documented sinusitis.

or

O. Any other manifestation(s) of HIV infection (including any listed in 114.08A-N, but without the requisite findings, e.g., oral candidiasis not meeting the criteria in 114.08F, diarrhea not meeting the criteria in 114.08J, or any other manifestation(s), e.g., oral hairy leukoplakia, hepatomegaly), resulting in one of the following:

1. For children from birth to attainment of age 1, at least one of the criteria in paragraphs A-E of 112.12; or

2. For children age 1 to attainment of age 3, at least one of the appropriate age-group criteria in paragraph B1 of 112.02; or

3. For children age 3 to attainment of age 18, at least two of the appropriate age-group criteria in paragraph B2 of 112.02.

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